UNITED STATES DISTRICT COURT
FOR THE
DISTRICT OF VERMONT

BLUE CROSS AND BLUE SHIELD OF VERMONT and THE VERMONT HEALTH PLAN, Plaintiffs, v. TEVA PHARMACEUTICAL INDUSTRIES, LTD., TEVA PHARMACEUTICALS USA, INC., TEVA SALES & MARKETING, INC., and TEVA NEUROSCIENCE, INC., Defendants.	)	Case No. 5:22-cv-159

OPINION AND ORDER ON MOTIONS TO DISMISS
(Docs. 48, 49)

In this putative class action, plaintiffs Blue Cross and Blue Shield of Vermont ("BCBSVT"), a Vermont nonprofit hospital service corporation and nonprofit medical service corporation, and The Vermont Health Plan ("TVHP"), a health maintenance organization and for-profit subsidiary of BCBSVT, sue the four above-captioned defendants alleging a "decade-long anticompetitive scheme to thwart competition to induce health insurers and health plans in the United States to pay billions for its excessively priced multiple sclerosis drug" Copaxone. (Doc. 1 ¶¶ 1, 4, 24–25.) Plaintiffs assert the following six counts: (1) violation of state antitrust statutes: monopolization; (2) violation of state antitrust laws: attempted monopolization; (3) violation of state antitrust statutes: contract, combination, or conspiracy to restrain trade; (4) violation of the Sherman Act, 15 U.S.C. §§ 1 or 2; (5) violations of state consumer protection acts; and (6) unjust enrichment.

The court denied Defendants' motion to change venue or stay the case in November 2022. (Doc. 45.) Two motions are currently pending, both filed in December 2022. First, Teva Pharmaceutical Industries, Ltd.—an Israeli corporation—has filed a Motion to Dismiss for Lack of Personal Jurisdiction under Fed. R. Civ. P. 12(b)(2). (Doc. 48.) Second, all Defendants have filed a Motion to Dismiss for Failure to State a Claim under Fed. R. Civ. P. 12(b)(6). (Doc. 49.) Briefing is now complete.[1] The court heard argument on the motions on July 14, 2023, and took them under advisement on that date.

Background

Plaintiffs' 386-paragraph complaint refers to all four defendants collectively as "Teva" (Doc. 1 ¶ 31) and includes the following allegations.[2] Additional details are set forth in the analysis as necessary below.

I. Therapeutic Drug Regulation and Marketing[3]

Because this case involves therapeutic drugs for human use, it is necessary to briefly outline some of the relevant regulatory backdrop and market structures. The 1938 federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. ("FDCA"), established "a system of premarket

[1] And extensive—in briefing the Rule 12(b)(6) motion, the parties have used every page of the overlength memoranda that the court authorized in a prior order (Doc. 43).

[2] Many of the allegations in the complaint draw on a September 2020 report from the United States House Committee on Oversight and Reform. *See* Staff of H. Comm. on Oversight & Reform, 116th Cong., Rep. on Drug Pricing Investigation: Teva—Copaxone (Sept. 2020), https://oversightdemocrats.house.gov/sites/democrats.oversight.house.gov/files/Teva%20Staff%20Report%2009-30-2020.pdf [https://perma.cc/N5BJ-HGXX] [hereinafter "House Report"]. The parties agreed at the July 2023 hearing that the House Report is incorporated into the complaint by reference and that the court can consider statements and allegations in the House Report and draw inferences from that report for purposes of the Rule 12(b)(6) motion.

[3] Although the complaint includes allegations on this topic (*see* Doc. 1 ¶¶ 76–80), the court cites legal authorities below for background on these undisputed points regarding the relevant regulatory framework.

approval for drugs." *Kellogg v. Wyeth*, 612 F. Supp. 2d 421, 424 (D. Vt. 2008) (citing *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 612 (1973)). Under the FDCA, "a new drug could not be marketed unless it was shown to be safe for its intended use." *Id.* "The Drug Amendments of 1962 amended the FDCA to require that new drugs be both safe and effective for their intended use." *Id.* The Food and Drug Administration ("FDA") is charged with "protect[ing] the public health by ensuring that," among other things, "human . . . drugs are safe and effective." 21 U.S.C. § 393(b)(2)(B).

"In order to market a new drug one must file a New Drug Application ('NDA') with the FDA . . . ." *Kellogg*, 612 F. Supp. 2d at 424. Federal law requires detailed documentation in each NDA. *See* 21 U.S.C. § 355(b)(1). As Plaintiffs put it: "The process to obtain FDA approval for an NDA is lengthy and very expensive." (Doc. 1 ¶ 76.) The FDA maintains a public list of drugs that have been approved for safety and effectiveness. 21 U.S.C. § 355(j)(7).

When such a publicly listed drug loses patent protection, companies "may seek permission from the FDA to market a generic version of the drug." *Kellogg*, 612 F. Supp. 2d at 425. "The Drug Price Competition and Patent Term Restoration Act of 1984 ('Hatch-Waxman Amendments') amended the FDCA to authorize an abbreviated new drug application ('ANDA') process for generic drugs that are bioequivalent to approved new drugs." *Id.*; *see also* 21 U.S.C. § 355(j). "The ANDA applicant is not required to conduct its own safety and effectiveness testing, but is permitted to rely upon the safety and effectiveness evidence presented in the NDA for the listed drug." *Kellogg*, 612 F. Supp. 2d at 425. In addition to the ANDA pathway under 21 U.S.C. § 355(j), a second abbreviated pathway to approval for a drug is available under 21 U.S.C. § 355(b)(2).

Although these two pathways simplify the regulatory hurdles for generic drug approval, generics are still "prohibited from infringing the brand's patents"; thus "when a generic competitor submits an ANDA, it must provide a 'certification' with respect to each unexpired patent related to the brand drug's production." *United Food & Com. Workers Local 1776 & Participating Emps. Health & Welfare Fund v. Takeda Pharm. Co.*, 11 F.4th 118, 125 (2d Cir. 2021). "The certification alerts the FDA to the relevant patent and explains why the proposed generic would not infringe it." *Id.* Under the Hatch-Waxman Act, a "Paragraph IV" certification states that the patent "is invalid or will not be infringed by the manufacture, use, or sale of the new drug." 21 U.S.C. § 355(j)(2)(A)(vii)(IV).[4]

Paragraph IV certifications "activate powerful rights and restrictions on behalf of the patent-holding company." *United Food & Com. Workers Local 1776*, 11 F.4th at 125. Such certifications trigger a "'highly artificial act of infringement,' permitting the brand manufacturer to sue the ANDA applicant." *Id.* (quoting *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990)). "If the brand chooses to sue, the FDA is automatically prevented from approving the ANDA for the earlier of thirty months or the outcome of the litigation." *Id.*

II. Multiple Sclerosis; Copaxone

Multiple sclerosis ("MS") is a disease that causes the body's immune system to attack the central nervous system, resulting in a range of symptoms. (Doc. 1 ¶ 2.) The most common form of MS—relapsing-remitting multiple sclerosis ("RRMS")—is characterized by "clearly defined attacks of new or increasing symptoms followed by periods of remission, during which symptoms partially or completely subside." (*Id.*); *see also Multiple Sclerosis (MS)*, Stedman's

[4] There are also "section viii" certifications, *see* 21 U.S.C. § 355(j)(2)(A)(viii), but that type of certification is not at issue in this case.

Medical Dictionary 802480, Westlaw (database updated Nov. 2014) (MS is a "common demyelinating disorder of the central nervous system, causing patches of sclerosis (plaques) in the brain and spinal cord; occurs primarily in young adults, and has protean clinical manifestations, depending on the location and size of the plaque"). There is no known cure for MS. (Doc. 1 ¶ 3.)

Glatiramer acetate ("GA") is a "chemically synthesized protein that simulates myelin," the protective protein that surrounds nerve fibers. (*Id.* ¶¶ 3, 51.) The precise mechanism that makes GA useful as an MS "disease-modifying therapy" (*id.* ¶ 51) is not relevant here[5] but, generally, GA "blocks or otherwise interrupts the immune system attacks associated with RRMS," thereby helping to alleviate MS symptoms. (*Id.* ¶¶ 3, 51.) The drug must be administered by injection. (*Id.* ¶ 3.)

Teva has licensed the rights to GA since 1987 and claims to hold all patents on the drug. (*Id.* ¶ 4; *see id.* ¶ 53.) GA is the active ingredient in Teva's brand-name drug Copaxone. (*Id.* ¶¶ 4, 51.) The FDA approved Copaxone for treatment of RRMS in 1996. (*Id.* ¶ 55.) Teva began selling Copaxone in March 1997. (*Id.* ¶¶ 5, 56.) At that time, Teva set the price for a monthly course of Copaxone treatment at $769.15. (*Id.* ¶ 5.)

The original version of Copaxone came in a 20 mg dose that was to be taken once daily. (*Id.* ¶ 166.) Patent exclusivity on 20 mg Copaxone was set to expire in 2015. (*Id.* ¶¶ 157, 166.) Well before then, senior Teva executives began holding meetings on Copaxone "Life Cycle Management" ("LCM") in 2002. (*Id.* ¶ 176.) Plaintiffs allege that LCM is "an industry term for the use of incremental research to extend a profitable drug's market monopoly." (*Id.*) One

[5] Defendants assert that "the way it works to treat MS is not fully understood." (Doc. 49 at 25.)

objective of Teva's LCM initiative was to "[m]inimize the risk of generic competition." (*Id.* (alteration in original).)

III. Teva's Alleged Anticompetitive Conduct

Plaintiffs allege that, in the following years, Teva engaged in "an anticompetitive scheme that caused health care payors, like Plaintiffs, in the United States to substantially overpay for glatiramer acetate." (*Id.* ¶ 7.) Plaintiffs allege that Teva "began by abusing patent litigation and the FDA's citizen petition process, to artificially prolong Copaxone's patent exclusivity and block lower-cost generics from entering the market." (*Id.* ¶ 8.) Plaintiffs further allege that after generics entered the market, Teva used "myriad" practices to suppress generic competition. (*Id.* ¶ 9.) Those alleged practices include a "product-hop scheme" to induce patients and doctors to switch to a new 40 mg, three-times-per-week GA formulation. (*Id.* ¶ 12.)

A. Alleged Anticompetitive Conduct to Delay Generic Entry

Generic pharmaceutical manufacturer Sandoz, Inc. ("Sandoz") submitted an ANDA to the FDA in December 2007 for Glatopa (Glatiramer Acetate) 20 mg. (*See* Doc. 1 ¶ 92 & n.51.)[6] Generic pharmaceutical manufacturer Mylan Pharmaceuticals Inc. ("Mylan") filed an ANDA for a 20 mg GA product in June 2009. (*See* Doc. 1 ¶ 198 (noting that Mylan is a manufacturer of a generic version of GA)); *see also Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 876 F. Supp. 2d 295, 307–08 (S.D.N.Y. 2012) (noting that Mylan submitted an ANDA for its GA product on June 29, 2009), *aff'd in part, rev'd in part, and remanded*, 723 F.3d 1363 (Fed. Cir. 2013), *vacated and remanded*, 574 U.S. 318 (2015). The generic competition that Teva executives contemplated in

[6] *See also, e.g.*, Letter from Acting Deputy Director, FDA Center for Drug Evaluation and Research, Offices of Regulatory Operations and Generic Drugs, to Sandoz, Inc. regarding ANDA 090218 (Apr. 16, 2015) (referencing December 27, 2007 filing date), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/090218Orig1s000ltr.pdf [https://perma.cc/2NFY-NG6Q].

2002 was beginning to materialize. Plaintiffs allege that Teva sought to delay generic entry by filing citizen petitions and by engaging in patent litigation. Plaintiffs contend that the citizen petitions and the patent lawsuits were all "objectively baseless." (Doc. 1 ¶ 94.) The court reviews that alleged conduct below.

1. Citizen Petitions

Federal regulations permit any "interested person"[7] to "petition" the FDA Commissioner to "issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action." 21 C.F.R. § 10.25(a). As relevant here, such petitions may be "in the form for a citizen petition in § 10.30." *Id.* § 10.25(a)(2). Plaintiffs observe that, "[i]n theory, citizen petitions could raise concerns that a drug is unsafe." (Doc. 1 ¶ 87.) But such petitions can also delay the approval of drug applications.[8] Recognizing the possibility of delay resulting from the citizen petition process, Congress has required that, where a written citizen petition under § 10.30 is submitted after September 27, 2007, the FDA must not delay the approval of drug applications unless the petition is "necessary to protect the public health." 21 U.S.C. § 355(q)(1)(A)(ii); *see also* 21 C.F.R. § 10.31.

Within 12 months of Sandoz's December 2007 ANDA, Teva filed the first of eight citizen petitions regarding GA products. (*See* Doc. 1 ¶ 89 & n.47.) In that first petition, Teva requested that the FDA Commissioner not approve or accept for filing any ANDA or 505(b)(2)

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[7] "Person" is defined to include "an individual, partnership, corporation, association, or other legal entity." 21 C.F.R. § 10.3(a).

[8] *See, e.g.*, Michael A. Carrier & Carl Minniti, *Citizen Petitions: Long, Late-Filed, and At-Last Denied*, 66 Am. U. L. Rev. 305, 314 (2016) (asserting that "[b]rand firms' use of citizen petitions could be a valuable addition" to a strategy of delaying generic entry); *see also* Michael A. Carrier & Daryl Wander, *Citizen Petitions: An Empirical Study*, 34 Cardozo L. Rev. 249, 251 (2012) (citizen petitions are a "potentially delaying activity").

application[9] "for a purported generic version or other pharmaceutical alternative to Copaxone" because "the clinically active polypeptide sequences in Copaxone® (glatiramer acetate injection) have not been sufficiently well defined to enable an ANDA or 505(b)(2) applicant to conclusively demonstrate that the clinically active polypeptide sequences in its purported generic product are qualitatively and quantitatively 'the same as' those in Copaxone®." Teva Neuroscience, Inc., Citizen Petition at 1–2, No. FDA-2008-P-0529 (Sept. 26, 2008), https://www.regulations.gov/document/FDA-2008-P-0529-0001. Teva further requested that, if the FDA did accept an ANDA that cites Copaxone as the reference listed drug, the ANDA should be converted to a 505(b)(2) application and the FDA should "not approve any such application for a follow-on glatiramoid product, including glatiramer acetate, unless the applicant conducts clinical safety and efficacy studies" and "[n]o such product may be assigned an 'AB' therapeutic equivalence rating." *Id.* at 2.

In March 2009—with Sandoz's and Mylan's ANDAs still pending—the FDA denied Teva's 2008 citizen petition "without comment on the requirements for approval of any ANDA or NDA for a glatiramer acetate injection drug product." FDA Petition Denial at 4, No. FDA-2008-P-0529 (Mar. 25, 2009), https://www.regulations.gov/document/FDA-2008-P-0529-0007. The agency reasoned that "it would be premature and inappropriate" to express any position on whether to approve any ANDA or NDA for any GA injection product. *Id.* at 3. "Such an action could, in effect, render a decision on a specific aspect of an ANDA or NDA before the Agency has had an opportunity either to fully consider specific data and information in such an application or to provide the procedural rights that accompany FDA actions or applications." *Id.*

[9] A "505(b)(2) application" is an application under the second abbreviated pathway mentioned above: 21 U.S.C. § 355(b)(2).

The FDA declined to permit a citizen petition to "short-circuit" the application review process. *Id.* at 4.

Teva filed seven additional citizen petitions regarding GA products between November 2009 and March 2015. One of those additional petitions—discussed below—was filed on December 5, 2013. (*See* Doc. 1 ¶ 89 n.47.) In each petition, Teva made arguments similar to the arguments in the 2008 citizen petition. (*Id.* ¶ 90.) Teva withdrew the citizen petition that it filed in September 2013, and the FDA denied five of the citizen petitions without commenting on the specific requirements for approval of any ANDA for a GA injection drug product. (*See id.* ¶ 91 & n.49.) The FDA denied the last filed citizen petition (the eighth) on the merits on April 16, 2015—the same date that it approved Sandoz's ANDA for 20 mg Glatopa. (*Id.* ¶ 92.)

2. Patent Litigation

Teva also filed numerous patent-infringement lawsuits in the years before the FDA approved the relevant generic GA products. (*Id.* ¶¶ 22(C), 85.) Acting on its rights under Paragraph IV certifications, Teva sued Sandoz in 2008 and then sued Mylan in 2009 alleging infringement of Teva's patents for improved compositions of "copolymer-1," the active ingredient in Copaxone.[10] Those Hatch-Waxman Act lawsuits triggered statutory 30-month stays of FDA approval of Sandoz and Mylan's ANDAs; the stays expired in January 2011 and March 2012, respectively. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

After consolidating the 2008 and 2009 Hatch-Waxman cases, the district court ruled in June 2012 that Mylan's and Sandoz's ANDAs were infringing and that none of Teva's asserted

[10] GA is also known as "copolymer 1." *In re: Copaxone Consol. Cases.*, 906 F.3d 1013, 1017 (Fed. Cir. 2018).

claims were invalid or unenforceable. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 876 F. Supp. 2d 295, 419 (S.D.N.Y. 2012) (Jones, J.). The district court then entered an order that, among other things, enjoined Sandoz and Mylan from marketing their generic GA products until September 1, 2015. Final Judgment Order ¶¶ 11–12, *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, No. 08-CV-7611 (S.D.N.Y. July 24, 2012), ECF No. 338 (citing 35 U.S.C. § 283).

Following an appeal to the Federal Circuit, 723 F.3d 1363 (Fed. Cir. 2013), the district court on remand entered a modified final judgment shortening the injunction and permitting generic launch in May 2014. *See* Modified Final Judgment Order, *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, No. 08-CV-7611 (S.D.N.Y. Dec. 20, 2013), ECF No. 355. After further appeal to the Supreme Court, 574 U.S. 318 (2015), the litigation resulted with conclusions that some of Teva's claims were valid and infringed and that other claims were invalid for indefiniteness. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1338 (Fed. Cir. 2015). Judge Mayer dissented, reasoning that the case should be remanded for factual findings on indefiniteness. *Id.* at 1349 (Mayer, J., dissenting).

Teva filed multiple other suits against generic manufacturers. One suit that Teva filed against Mylan in 2009 was dismissed for failure to prosecute. *Teva Pharms. USA, Inc. v. Mylan Pharms., Inc.*, No. 09-cv-152 (N.D.W.Va. July 2, 2010), ECF No. 24. Lawsuits that Teva filed against Sandoz in 2009 and Mylan in 2010 were dismissed at the Rule 12 stage. *Teva Pharms. USA, Inc. v. Sandoz Inc.*, Nos. 09 Civ. 10112, 10 Civ. 7246, 2013 WL 3732867 (S.D.N.Y. July 16, 2013), *appeal voluntarily dismissed*, No. 13-1572 (Fed. Cir. Nov. 20, 2013). A pair of lawsuits that Teva filed against another generic manufacturer in 2012 were voluntarily dismissed. *See Teva Pharms. USA, Inc. v. Synthon Pharms., Inc.*, No. 12-2556 (S.D.N.Y. Sept. 18, 2014), ECF No. 53; *Teva Pharms. USA, Inc. v. Synthon Pharms., Inc.*, No. 12-cv-179

(E.D.N.C. June 1, 2012), ECF No. 12. Another pair of patent lawsuits that Teva filed in the District of New Jersey in 2015 also ended with dismissals. *See* Pls.' Notice of Voluntary Dismissal, *Teva Pharms. USA, Inc. v. Dr. Reddy's Lab'ys, Ltd.*, No. 15-cv-471 (D.N.J. June 26, 2015), ECF No. 39; Stipulation of Dismissal and Order, *Teva Pharms. USA, Inc. v. Synthon Pharms., Inc.*, No. 15-472 (D.N.J. Mar. 24, 2015), ECF No. 10.

Meanwhile, in June 2009, Teva executives prepared a presentation that described "a need to develop a low frequency formulation of GA to ensure the competitiveness of Copaxone in the future." (Doc. 1 ¶ 177.) The presentation suggested studying a regimen of 40 mg GA doses injected two to three times per week. (*See id.* ¶ 177–178.) The FDA granted approval for Teva to market a three-times-weekly 40 mg dose on January 28, 2014. (*Id.* ¶ 167.) Teva released 40 mg Copaxone the following day. (*Id.*) Teva simultaneously issued a press release billing the 40 mg product as "a significant advancement for patients." (*Id.* ¶ 182.) Patent litigation related to the 40 mg GA product followed.

Teva sued Sandoz and another generic manufacturer in September 2014, alleging patent infringement based on an ANDA that Sandoz filed seeking approval for a 40 mg product purporting to be generic to Copaxone. Compl. ¶ 1, *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, No. 14-cv-1171 (D. Del. Sept. 10, 2014). As with the 2008 and 2009 Hatch-Waxman Act suits, Teva's 2014 suit triggered a statutory 30-month stay of FDA approval of Sandoz's 40 mg product. *See* 21 U.S.C. § 355(j)(5)(B)(iii). The 2014 suit became the lead case in a consolidated group of cases filed in the District of Delaware, including *Teva Pharmaceuticals USA Inc. v. Synthon Pharmaceuticals, Inc.*, No. 14-cv-1419; *Teva Pharmaceuticals USA Inc. v. Mylan Pharmaceuticals Inc.*, No. 14-cv-1278; and *Teva Pharmaceuticals USA Inc. v. Amneal Pharmaceuticals LLC*, No. 15-cv-124. That litigation proceeded to a seven-day bench trial in

2016 before Judge Gregory M. Sleet, who issued findings of fact and conclusions of law and determined—by clear and convincing evidence—that all of the asserted claims of the patents-in-suit were invalid as obvious. *In re Copaxone Consol. Cases*, No. 14-1171, 2017 WL 401943 (D. Del. Jan. 30, 2017).

The consolidated cases concluded with the Federal Circuit's unanimous 2018 decision affirming the district court's holding that Teva's asserted claims of patents directed to Copaxone 40 mg were "invalid as obvious under 35 U.S.C. § 103." *In re: Copaxone Consol. Cases.*, 906 F.3d 1013, 1016 (Fed. Cir. 2018). On the same day that the Federal Circuit affirmed the district court, that court also affirmed the Patent Trial and Appeal Board's ("PTAB") decisions finding Copaxone 40 mg unpatentable as "obvious." *Yeda Rsch. v. Mylan Pharms. Inc.*, 906 F.3d 1031 (Fed. Cir. 2018).

Teva filed a substantively identical case in the Northern District of West Virginia in 2014; that case was stayed for much of its duration and was ultimately dismissed after the District of Delaware's 2016 bench trial and judgment against Teva. Stipulation & Order Dismissing Case with Prejudice, *Teva Pharms. USA, Inc. v. Mylan Pharms.*, No. 14-cv-167 (N.D.W.Va. June 27, 2017), ECF No. 67. Teva also voluntarily dismissed a similar case that it filed in 2014 in the Middle District of North Carolina. Pls.' Notice of Voluntary Dismissal, *Teva Pharms. USA, Inc. v. Synthon Pharms., Inc.*, No. 14-cv-975 (M.D.N.C. Feb. 12, 2015), ECF No. 9.

3. Lawsuits Against the FDA

In addition to the citizen petitions and patent litigation cited above, Plaintiffs note two instances in which Teva sued the FDA. (Doc. 1 ¶ 22(C).) Teva sued the FDA on May 9, 2014 challenging the FDA's denial of the December 5, 2013 citizen petition. Complaint, *Teva Pharm.*

Indus. Ltd. v. Sebelius, No. 14-cv-786 (D.D.C. May 9, 2014). Judge Huvelle dismissed that case on May 14, 2014 after finding that "the case is not ripe and therefore the Court lacks jurisdiction." *Sebelius*, No. 14-cv-786 (D.D.C. May 14, 2014), ECF No. 36. Teva sued the FDA again in March 2020 for alleged "refusal to treat Copaxone as a biologic." (Doc. 1 ¶ 22(C)); *see also* Complaint, *Teva Pharm. USA, Inc. v. FDA*, No. 20-cv-808 (D.D.C. Mar. 24, 2020). Chief Judge Howell granted summary judgment against Teva in December 2020. *Teva Pharm. USA, Inc. v. FDA*, 514 F. Supp. 3d 66 (D.D.C. 2020).

B. Alleged Anticompetitive Conduct to Stifle Competition from Generics

As noted above, the FDA approved the first generic GA medication—Sandoz's 20 mg Glatopa—on April 16, 2015. (Doc. 1 ¶ 92.) Mylan introduced a generic version of Copaxone 40 mg in October 2017. (*Id.* ¶ 186.) Plaintiffs allege that, before and after these generics entered the market, Teva used "myriad anticompetitive, unfair, and deceptive practices" to stifle competition from the generics. (*Id.* ¶ 9.) The court reviews the allegations of each of these alleged practices below.

1. Copay Assistance

Plaintiffs note that patient cost-sharing obligations (or "co-pays") serve as a check on drug costs by making plan members sensitive to price. (Doc. 1 ¶¶ 107–109.) Plaintiffs assert that Teva "conspired with a specialty pharmacy, non-profit foundations, and other entities to implement an anticompetitive scheme to undermine and circumvent" those health plan cost-sharing provisions. (*Id.* ¶ 106.) As described in more detail below, this alleged scheme involved patient assistance programs ("PAPs") directed to members of private health plans and to Medicare recipients and members of other federal health plans.

a. Assistance to Members of Private Health Plans

Plaintiffs allege that "Teva knew that if members of private health plans were exposed to high cost-sharing obligations, substantially fewer patients would have purchased Copaxone and Teva would have been forced to lower prices or lose sales." (Doc. 1 ¶ 110.) Plaintiffs further allege that "[i]nstead of lowering the price to make Copaxone more affordable, Teva instead devised a scheme to bypass these price controls by paying the cost-sharing obligations on behalf of health plan members." (*Id.* ¶ 111.) The alleged scheme came in the form of a "coupon" service—known as "Copaxone Co-Pay Solutions"—as part of Teva's "Shared Solutions" patient-services program. (*Id.* ¶ 113.)

According to Plaintiffs, Teva provided "coupon" cards directly to private health plan members. (*Id.* ¶ 111.) "When a member went to a pharmacy to fill a Copaxone prescription, the pharmacy would accept the coupon from the participant in lieu of collecting the participant's cost-sharing obligation, and Teva would pay the pharmacy for the value of the coupon." (*Id.*) The health plan member thus paid little or nothing out of pocket for Copaxone and would pay less for Copaxone than they would have paid for the generic GA drug. (*Id.*) Plaintiffs allege that Teva thereby "shielded the decisionmakers (i.e., plan members) from the impact of Copaxone's excessive price, thereby inducing further sales, all while exposing the health plan payors, who pay the majority of any drug's costs, to the ever-increasing list price." (*Id.* ¶ 112.)

b. Assistance to Medicare Recipients and Other Federal Plans

The federal Anti-Kickback Statute ("AKS") imposes criminal liability upon anyone who "knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person":

> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program.

42 U.S.C. § 1320a-7b(b)(2). Teva therefore could not lawfully subsidize the co-insurance or other cost-sharing obligations of federal health plan members. *See* Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70,623, 70,625 (Nov. 22, 2005) (stating that the AKS "squarely prohibit[s]" cost-sharing subsidies provided by pharmaceutical manufacturer patient assistance programs "because the manufacturer would be giving something of value (i.e., the subsidy) to beneficiaries to use its product"). The bulletin explains:

> Where a manufacturer PAP offers subsidies tied to the use of the manufacturer's products (often expensive drugs used by patients with chronic illnesses), the subsidies present all of the usual risks of fraud and abuse associated with kickbacks, including steering beneficiaries to particular drugs; increasing costs to Medicare; providing a financial advantage over competing drugs; and reducing beneficiaries' incentives to locate and use less expensive, equally effective drugs.

Id. Teva knew about the AKS provisions and that it could not pursue its "coupon" strategy with respect to Medicare recipients and other federal health plan members. (Doc. 1 ¶ 118.)

Instead, Teva allegedly devised a way to "cheat the system." (*Id.* ¶ 121.) As the Special Advisory Bulletin notes, "pharmaceutical manufacturers can effectively contribute to the pharmaceutical safety net by making cash donations to independent, bona fide charitable assistance programs." Special Advisory Bulletin, 70 Fed. Reg. at 70,626. The AKS does not prohibit such donations provided that "appropriate safeguards" are in place. *Id.* at 70,625; *see also id.* at 70,626 (listing five requirements and summarizing: "Simply put, the independent charity PAP must not function as a conduit for payments by the pharmaceutical manufacturer to

patients and must not impermissibly influence beneficiaries' drug choices."). Plaintiffs assert that Teva knew about the prohibition on using charity as a conduit for payments to Medicare patients, but nevertheless used charitable organizations as "pass-through vehicles" in violation of the AKS. (Doc. 1 ¶¶ 125, 145.)

In particular, Plaintiffs allege that, between 2006 and 2018, Teva "knowingly and willfully" violated the AKS "by paying over $300 million to two third-party foundations, Chronic Disease Fund and The Assistance Fund, to cover the Medicare co-pay obligations of Copaxone patients." (*Id.* ¶¶ 125, 149.) In 2020, the United States sued Teva in a civil action under the False Claims Act based on that alleged conduct in violation of the AKS. *United States v. Teva Pharms. USA, Inc.*, 560 F. Supp. 3d 412, 416 (D. Mass. 2021) (the "AKS lawsuit"). Litigation in that lawsuit is ongoing.[11]

Plaintiffs further allege that Teva conspired with multiple entities to facilitate the kickback scheme. Plaintiffs allege that Teva referred Medicare-eligible Copaxone patients to Advanced Care Scripts, Inc. ("Advanced Care")—a specialty pharmacy[12]—which would then arrange for the patients to obtain co-pay assistance from Chronic Disease Fund and The Assistance Fund. (Doc. 1 ¶ 127.) The amounts of Teva's donations each year were based on its calculation of the amounts that those funds would need "to specifically fund Copaxone co-pay assistance for Medicare recipients." (*Id.* ¶ 128.) And Teva would use information that it

[11] Teva filed a motion to dismiss, which the district court granted in part and denied in part. 560 F. Supp. 3d at 416. The district court denied Teva's motion for summary judgment on July 14, 2023. *United States v. Teva Pharms. USA, Inc.*, No. 20-11548, 2023 WL 4565105 (D. Mass. July 14, 2023). The First Circuit granted permission to appeal the summary judgment ruling in November 2023. *United States v. Teva Pharms. USA, Inc.*, No. 23-8028 (1st Cir. Nov. 17, 2023).

[12] *See generally High Mountain Corp. v. MVP Health Care, Inc.*, 592 F. Supp. 3d 325, 338–39 (D. Vt. 2022) (discussing specialty pharmacies).

received from Advanced Care on new patients awaiting copay assistance and would make supplemental "donations" to the assistance funds that were "earmarked to fund assistance for these new patients." (*Id.* ¶ 129.) Teva "took steps to ensure its 'donations' would be used exclusively for Copaxone and not for other MS medications." (*Id.* ¶ 134.) Teva also "raised the amounts of its 'donations' in lockstep with its increases to the price of Copaxone to ensure that Medicare recipients remained insulted from their price hikes." (*Id.* ¶ 140.)

Advanced Care's cofounders, Edward Hensley and Jeff Spafford, left that company in 2009 and founded The Assistance Found as a foundation modeled after Chronic Disease Fund. (*Id.* ¶ 131.) In February 2015, Hensley and Spafford founded a for-profit business called AssistRx. (*Id.* ¶ 132.) AssistRx "assumed Advanced Care's role of arranging Medicare co-pay assistance for Copaxone patients referred by Teva." (*Id.*) Advanced Care and AssistRx obtained millions of dollars in service fees that Teva paid. (*Id.* ¶ 133.) Advanced Care also profited from additional Copaxone sales to Medicare patients. (*Id.*)

2. Alleged Product-Hopping

"Product hopping" is "conduct by a monopolist to perpetuate patent exclusivity through successive products." *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 643 (2d Cir. 2015). Plaintiffs allege that Teva engaged in such conduct by "coerc[ing] and induc[ing] doctors, pharmacies, and patients to switch from 20 mg Copaxone to 40 mg Copaxone before Glatopa or other 20 mg generics became available for purchase." (Doc. 1 ¶ 168.) Plaintiffs allege that this was a "multi-pronged campaign" (*id.*) that involved the conduct described below. Plaintiffs further allege that the "product hop" was the result of "more than a decade of planning," including the 2002 LCM meetings and the 2009 presentation regarding the need to develop a low-frequency formulation of GA. (*Id.* ¶¶ 176, 177.) According to Plaintiffs,

by December 2015, Teva converted 76.9% of Copaxone patients to 40 mg and limited generic 20 mg market share to 19.3%. (*Id.* ¶ 174.) The alleged product hop ultimately allowed Teva to avoid generic competition "until at least 2017," when Mylan introduced a generic version of Copaxone 40 mg. (*Id.* ¶¶ 183, 186.)

a. Price Manipulation

Plaintiffs allege that Teva "manipulated the pricing of both versions of Copaxone to induce patients to switch to 40 mg Copaxone." (*Id.* ¶ 169.) After the FDA approved Copaxone 40 mg in 2014, Teva initially priced that version as "slightly less expensive per week of treatment than Copaxone 20 mg." (*Id.*) "Shortly thereafter, Teva increased the price of 20 mg Copaxone by 9.8%." (*Id.*)

b. Pressure on PBMs

Teva allegedly pressured pharmacy benefit managers (PBMs)[13] to make 40 mg Copaxone available to participants of health plans and "threatened PBMs that it would stop paying the PBMs rebates on 20 mg Copaxone unless the PBMs made 40 mg Copaxone available on their formularies."[14] (Doc. 1 ¶ 170.) Teva followed through on that threat "[o]n at least one occasion" by "eliminating Copaxone rebates for at least one PBM that failed to add 40 mg Copaxone to its formulary." (*Id.*) That PBM added 40 mg Copaxone to its formulary the next year. (*Id.*)

[13] PBMs "manage[] and administer[] prescription drug benefits on behalf of" health benefit plans. (Doc. 1 ¶ 71); *see also, e.g.*, 8 V.S.A. § 4089j(a)(2) (defining PBM for purposes of Vermont law regarding prescription drug purchasing).

[14] PBMs design "formularies," which are essentially "lists of drugs that are available to members of a health plan." (Doc. 1 ¶ 73.) "Formularies are typically 'tiered,' meaning that certain drugs are preferred over others for various medical conditions." (*Id.*)

c. "Copaxone Conversion Initiative"

Teva also allegedly "colluded with PBMs to implement a so-called 'Copaxone conversion initiative.'" (*Id.* ¶ 171.) According to Plaintiffs, Teva contracted with one or more PBMs under which the PBMs committed to convert Copaxone 20 mg patients to Copaxone 40 mg. (*Id.*) Under this program, the PBMs would contact the prescribers to make them aware of which patients were still on Copaxone 20 mg and encourage them to switch those patients to the 40 mg version. (*Id.*)

d. Outreach to Physicians

A fourth alleged category of conduct in the alleged product hop was Teva's effort to "directly target[] physicians with an intense outreach campaign." (*Id.* ¶ 172.) Members of Teva's sales force allegedly contacted physicians to tell them to:

> (i) "initiate and upgrade any remaining patients to TIW [three times weekly] Copaxone 40 mg"; (ii) "switch patients to TIW Copaxone 40 mg if payers force to generic GA for daily dose"; (iii) "Prescribe Copaxone DAW [Dispense as Written] for new and existing patients"; and (iv) "Encourage their patients to accept only branded Copaxone."

(*Id.* (alterations in original) (quoting House Report at 32).) Plaintiffs further allege that Teva "created financial incentives for its sales force to execute this plan, making their bonuses dependent entirely on the sales of 40 mg Copaxone." (*Id.*)

e. Plan to Discontinue Copay Assistance for 20 mg Copaxone

Finally, Plaintiffs allege that Teva "explored" a plan to switch patients to 40 mg Copaxone "by discontinuing copay assistance programs for the 20 mg dosage." (*Id.* ¶ 173.)

3. Additional Conduct After Mylan Introduced Generic GA in 2017

Plaintiffs allege that Teva engaged in three additional categories of anticompetitive tactics after Mylan introduced a lower-priced generic version of Copaxone 40 mg in October 2017. (Doc. 1 ¶ 186.)

a. "House Brand" Strategy

According to Plaintiffs, Teva implemented a "House Brand" strategy that involved "contracting with PBMs and specialty pharmacies to make Copaxone 40 mg the drug that was dispensed to health plan members." (*Id.* ¶ 187.) The strategy with respect to certain PBMs was to sign contracts "that restricted generic access at the formulary level." (*Id.* ¶ 189.) As to certain specialty pharmacies, Teva contracted "so that prescriptions for glatiramer acetate would be filled with brand, regardless of whether a generic was prescribed." (*Id.* ¶ 190.)

b. Dispense as Written ("DAW")

A provider can prohibit generic substitution for a medication that she prescribes by including a "Dispense as Written" ("DAW") notation. (*Id.* ¶ 195.) Teva campaigned to persuade doctors to write prescriptions for Copaxone as DAW by "misleadingly represent[ing] that patients would benefit from remaining on brand Copaxone." (*Id.* ¶ 197.) According to Plaintiffs, Teva and its sales representatives falsely told prescribers or misled them to believe that the generic GA products were only 80–85% as effective as Copaxone, and that Copaxone and generic GA were not interchangeable. (*Id.* ¶¶ 198–199.) By February 2018, 77% of Copaxone prescriptions were written with the DAW notation. (*Id.* ¶ 201.)

c. "Shared Solutions"

The "Copaxone Co-Pay Solutions" program discussed above is part of Teva's "Shared Solutions" patient-services program. (*Id.* ¶ 113.) The "Shared Solutions" program offers "a variety of services to Copaxone users, including providing free injection devices, free injection training, and assistance with obtaining insurance coverage." (*Id.* ¶ 205.) When physicians prescribed Copaxone, they would typically also submit enrollment forms to Shared Solutions on behalf of each new Copaxone patient. (*Id.* ¶ 206.)

Analysis

I. Defendants' Rule 12(b)(6) Motion to Dismiss

The court begins with Defendants' Rule 12(b)(6) motion. *See Chevron Corp. v. Naranjo*, 667 F.3d 232, 246 n.17 (2d Cir. 2012) (courts generally address challenges to personal jurisdiction before reaching the merits, but "with multiple defendants—over some of whom the court indisputably has personal jurisdiction—in which all defendants collectively challenge the legal sufficiency of the plaintiff's cause of action, we may address first the facial challenge to the underlying cause of action and, if we dismiss the claim in its entirety, decline to address the personal jurisdiction claims made by some defendants").

To survive Defendants' Rule 12(b)(6) motion to dismiss for failure to state a claim, Plaintiffs' complaint "must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Eastman Kodak Co. v. Henry Bath LLC*, 936 F.3d 86, 93 (2d Cir. 2019) (internal quotation marks omitted) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). In evaluating Defendants' Rule 12(b)(6) motion, the court must "draw[] all reasonable inferences in favor of the plaintiff[s]." *Biocad JSC v. F. Hoffman-La Roche*, 942 F.3d 88, 93 (2d Cir. 2019). "Dismissal is appropriate when 'it is clear from the face of the complaint . . . that the plaintiff's claims are barred as a matter of law.'" *Id.* (alteration in original) (quoting *Parkcentral Glob. Hub Ltd. v. Porsche Auto Holdings SE*, 763 F.3d 198, 208–09 (2d Cir. 2014)).

A. Sherman Act Claims (Count IV)

Plaintiffs' only claims under federal law are their claims in Count IV alleging violations of the Sherman Act, 15 U.S.C. §§ 1 or 2. "In the Sherman Act, Congress tasked courts with enforcing a policy of competition on the belief that market forces yield the best allocation of the Nation's resources." *Nat'l Collegiate Athletic Ass'n v. Alston*, 141 S. Ct. 2141, 2147 (2021)

(internal quotation marks omitted). Section 1 of the Sherman Act "applies only to concerted action" while Section 2 "covers both concerted and independent action, but only if that action monopolizes or threatens actual monopolization." *Am. Needle, Inc. v. Nat'l Football League*, 560 U.S. 183, 190 (2010) (cleaned up; internal quotation marks and citation omitted). "Concerted activity subject to § 1 is judged more sternly than unilateral activity under § 2." *Copperweld Corp. v. Indep. Tube Corp.*, 467 U.S. 752, 768 (1984). To survive a motion to dismiss, a Sherman Act claim must "(1) define the relevant [] market, (2) allege an antitrust injury, and (3) allege conduct in violation of antitrust laws." *Concord Assocs., L.P. v. Ent. Props. Tr.*, 817 F.3d 46, 52 (2d Cir. 2016) (quoting *N.Y. Medscan LLC v. N.Y. Univ. Sch. of Med.*, 430 F. Supp. 2d 140, 145 (S.D.N.Y.2006)). This applies to claims under both Sections 1 and 2. *Id.*

Plaintiffs' Sherman Act claims are based on alleged anticompetitive conduct that Plaintiffs claim either delayed generic market entry or limited generic uptake. Defendants assert that neither theory supports a claim. (Doc. 49 at 26.) Plaintiffs maintain that "each element of Teva's scheme was independently anticompetitive" and that all of the elements of the alleged scheme also had a "combined, synergistic impact." (Doc. 58 at 26.) The court considers both of the categories of alleged anticompetitive conduct below.

The complaint does not distinguish between the alleged violations of section 1 and section 2 of the Sherman Act. Four of the five counts concern alleged violations of state law, both antitrust and consumer protection statutes. The federal antitrust claim (Count IV) incorporates by reference the state law antitrust allegations: "For the reasons set forth in the above Counts, Defendants have violated §§ 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2." (Doc. 1 ¶ 295.) In considering the arguments for and against dismissal of the Sherman Act

claims, it is not necessary to distinguish between the section 1 claims of concerted action and the section 2 claims of monopolization. As it relates to allegations of delay in the availability of generic alternatives, the bases for the motion are the *Noerr-Pennington* doctrine, insufficient allegations of causation and time bar. These apply equally to both section 1 and section 2 claims. The effort to dismiss the claims on grounds related to delay in "uptake" or acceptance of the generic alternatives concerns measures taken by the Teva companies alone and are analyzed under section 2. In the end, these distinctions are not critical either to the motion to dismiss and the response or to the court's decision because the proposed defenses to the Sherman Act claim apply generally to both sections.

1. Alleged Conduct to Delay Generic Entry—Citizen Petitions and Lawsuits

Regarding the alleged conduct to delay market entry, Defendants argue that the citizen petitions and patent lawsuits are immune from antitrust liability under the *Noerr-Pennington* doctrine. (Doc. 49 at 40.) Defendants also argue that the petitions and lawsuits did not delay FDA approval of generic GA products, and that any claim premised on Teva's lawsuits or petitions is time-barred. (*Id.* at 44, 46.) The court examines each of these three arguments below.

a. *Noerr-Pennington*

The court begins by reviewing the *Noerr-Pennington* doctrine, the applicable exceptions, and the procedural considerations that are relevant at this stage of the case. "Generally, under the *Noerr-Pennington* doctrine, citizen petitions are immune from antitrust liability in light of the First Amendment." *In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 685–86 (2d Cir. 2009) (citing *E. R.R. Presidents Conf. v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961), and *United Mine Workers of Am. v. Pennington*, 381 U.S. 657 (1965)); *see also*

Primetime 24 Joint Venture v. Nat'l Broad. Co., 219 F.3d 92, 99 (2d Cir. 2000) (noting that the First Amendment right to petition the government generally shields "concerted actions before courts and administrative agencies" from liability under the Sherman Act). The same general immunity applies to patent lawsuits. *See, e.g.*, *In re Actos End-Payor Antitrust Litig.*, 417 F. Supp. 3d 352, 374 (S.D.N.Y. 2019) (recognizing that "[a] patentee who seeks to enforce its patent through litigation" generally enjoys *Noerr-Pennington* immunity).

But *Noerr-Pennington* protection "is not absolute." *DDAVP*, 585 F.3d at 686. "When petitioning activity ostensibly directed toward influencing governmental action is a sham to cover what is nothing more than an attempt to interfere directly with the business relationships of a competitor, then the application of the Sherman Act would be justified." *Id.* (cleaned up; quoting *Noerr*, 365 U.S. at 144).[15] The "sham" exception applies where a single petition or litigation was "(i) 'objectively baseless,' and (ii) 'an attempt to interfere directly with the business relationships of a competitor through the use of the governmental process—as opposed to the outcome of that process—as an anticompetitive weapon.'" *Primetime 24*, 219 F.3d at 100–01 (quoting *Pro. Real Est. Invs., Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60 (1993) [hereinafter *PRE*]).

However, "[i]n cases in which the defendant is accused of bringing *a whole series of legal proceedings*, the test is not retrospective but prospective." *Id.* at 101 (emphasis added; internal quotation marks omitted). Where the plaintiff alleges such "serial" sham litigation, it is irrelevant that some of the claims might have merit "as a matter of chance." *Id.* (quoting *USS-*

[15] In addition to the "sham" exception, there is also a "corruption" exception to the *Noerr-Pennington* doctrine. *See 360 Mortg. Grp., LLC v. Fortress Inv. Grp. LLC*, No. 19 Civ. 8760, 2020 WL 5259283, at *4 (S.D.N.Y. Sept. 3, 2020). Plaintiffs do not rely on that exception.

POSCO Indus. v. Contra Costa Cnty. Bldg. & Constr. Trades Council, AFL-CIO, 31 F.3d 800, 811 (9th Cir. 1994)). Instead, the court asks: "Were the legal filings made, not out of a genuine interest in redressing grievances, but as part of a pattern or practice of successive filings undertaken essentially for purposes of harassment?" *Id.* (quoting *USS-POSCO*, 31 F.3d at 811).

As to procedural considerations, the court observes that "[t]he *Noerr-Pennington* doctrine is generally raised as an affirmative defense." *360 Mortg. Grp., LLC v. Fortress Inv. Grp. LLC*, No. 19 Civ. 8760, 2020 WL 5259283, at *4 (S.D.N.Y. Sept. 3, 2020). As such, dismissal based on the *Noerr-Pennington* defense "is warranted only if 'it is clear from the face of the complaint, and matters of which the court may take judicial notice, that the plaintiff's claims are barred as a matter of law.'" *Id.* (quoting *Staehr v. Hartford Fin. Servs. Grp., Inc.*, 547 F.3d 406, 425 (2d Cir. 2008)). Dismissal of the claims at issue under *Noerr-Pennington* is appropriate only if "it is apparent from the face of the [complaint] that this defense necessarily applies." *Id.* Thus, Plaintiffs have "no affirmative obligation to plead facts to show that the *Noerr-Pennington* doctrine does not apply, i.e., that the sham exception applies."[16] *Id.*

With the above principles in mind, the court proceeds to consider the application of the *Noerr-Pennington* doctrine in this case. Here, Plaintiffs allege both varieties of the "sham" exception. They allege serial sham citizen petitions and patent litigation. (*See* Doc. 1 ¶¶ 89, 93; *see also* Doc. 58 at 31 (arguing that "Teva engaged in a pattern of successive litigation and

[16] Courts have arrived at various conclusions on this point. *See* 3 Antitrust Laws and Trade Regulation § 50.05[4][a] (2d ed.) (recognizing that some courts have held "that the burden is on the plaintiff to establish that the defense does not apply, although the scope of the burden has varied"); *see also Takeda Pharm. Co. v. Zydus Pharms. (USA) Inc.*, No. 21-2608, 2022 WL 17546949, at *2 n.3 (3d Cir. Dec. 9, 2022) ("Zydus had the burden of proving that Takeda is not entitled to *Noerr-Pennington* immunity . . . ."). This court finds that *360 Mortgage Group* is persuasive on the issue. Ultimately, however, the court's conclusion would be the same in this case regardless of the applicable burden.

citizen petitioning without regard to the merits and for the purpose of delaying competition").) Plaintiffs also invoke the two-step subjective-objective inquiry that applies to a single petition or litigation. (*See* Doc. 1 ¶¶ 91, 94, 96; *see also* Doc. 58 at 29–31 (arguing that Teva's patent litigation regarding Copaxone 40 mg was objectively and subjectively baseless).) The court begins with the more "exacting" standard that applies for a single petition or litigation. *See Tyco Healthcare Grp. LP v. Mut. Pharm. Co.*, 762 F.3d 1338, 1346 (Fed. Cir. 2014).[17]

i. Single Petition Variety of the Sham Exception

"A single lawsuit can violate antitrust law as long as it is both an objective and subjective sham." *DDAVP*, 585 F.3d at 686. A lawsuit is "objectively baseless" for purposes of the "sham" exception if "no reasonable litigant could realistically expect success on the merits." *PRE*, 508 U.S. at 60. The subjective prong asks whether the litigation was "an attempt to interfere directly with the business relationships of a competitor through the use of the governmental process—as opposed to the outcome of that process—as an anticompetitive weapon." *Id.* at 60–61 (cleaned up). This is an "exacting" standard, particularly in light of the presumption of patent validity under 35 U.S.C. § 282(a). *See Tyco Healthcare*, 762 F.3d

[17] For the *Noerr-Pennington* discussion below, the court analyzes authorities from within the Second Circuit, the Federal Circuit, and elsewhere. The court recognizes that some authorities hold that "whether conduct in procuring or enforcing a patent is sufficient to strip a patentee of its immunity from the antitrust laws is to be decided as a question of Federal Circuit law." *Applera Corp. v. MJ Res. Inc.*, 303 F. Supp. 2d 130, 133 n.11 (D. Conn. 2004) (quoting *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1068 (Fed. Cir. 1998) (en banc in relevant part)); *see also Xerox Corp. v. Media Sciences Int'l, Inc.*, 511 F. Supp. 2d 372, 387 n.9 (S.D.N.Y. 2007) (parties agreed that "Federal Circuit law is controlling on substantive issues of patent law implicated in the antitrust counterclaim"; citing *Nobelpharma*). It does not appear that the Second Circuit Court of Appeals has ruled on this choice-of-law question, and it is possible that the Second Circuit might decline to follow *Nobelpharma* and apply its own precedent. *Cf. Amphastar Pharms. Inc. v. Momenta Pharms., Inc.*, 850 F.3d 52, 56–57 (1st Cir. 2017) (noting that "*Nobelpharma* is not binding on us" and applying First Circuit precedent). In any case, the parties have not articulated any material difference between Federal Circuit and Second Circuit law on the issues discussed below.

at 1345–46; *In re Elysium Health-Chromadex Litig.*, 354 F. Supp. 3d 330, 336 (S.D.N.Y. 2019) ("The sham exception should be construed narrowly . . . .").

Plaintiffs allege that Teva's Hatch-Waxman lawsuits seeking to enforce its patents on Copaxone 40 mg were objectively baseless.[18] (Doc. 1 ¶¶ 93–94.) Teva responds that Plaintiffs' contention on that point is "conclusory," unsupported, and "contrary to the public record." (Doc. 49 at 42.) Teva maintains that its Copaxone 40 mg infringement suit was not a sham because it was "vigorously litigated, resulting in a seven-day bench trial, a detailed district court opinion, and a published opinion from the Federal Circuit"—i.e., *In re: Copaxone Consolidated Cases.*, 906 F.3d 1013 (Fed. Cir. 2018). (*Id.*) Plaintiffs do not dispute that procedural history but argue that it is not a basis for dismissal. (Doc. 58 at 30.) Plaintiffs assert that "[p]atent infringement lawsuits, even baseless ones, are typically fact-based and notoriously expensive to litigate; courts are reluctant to dismiss them at early stages." (*Id.* (footnote omitted).) In reply, Teva notes that patents on dosage changes have survived challenges and that the fact-based nature of patent cases proves that Teva had a good-faith basis to assert that its patent was valid. (Doc. 66 at 16 & n.3.)

For the reasons discussed below, the court concludes that the circumstances weigh against conferring *Noerr-Pennington* immunity at this early stage of the case. Teva brought the Copaxone 40 mg infringement suits at issue after the defendants in those cases filed ANDAs with Paragraph IV certifications. *See In re Copaxone Consol. Cases*, No. 14-1171, 2017 WL 401943, at *6–10 (D. Del. Jan. 30, 2017). That conduct raises two competing considerations.

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[18] As relevant to the subjective prong, Plaintiffs allege that "Teva misused patent litigation to interfere with competitors' business relationships and stifle competition." (Doc. 1 ¶ 96.) Defendants do not challenge the plausibility of Plaintiffs' allegations on the subjective prong.

On one hand, because the submission of an ANDA is by statutory definition an infringing act, "an infringement suit filed in response to an ANDA with a paragraph IV certification could only be objectively baseless if no reasonable person could disagree with the assertions of noninfringement or invalidity in the certification." *FTC v. AbbVie Inc.*, 976 F.3d 327, 361 (3d Cir. 2020).

On the other hand, Teva's Hatch-Waxman suits triggered the automatic 30-month stay, preventing the FDA from approving the ANDAs. And, as the Third Circuit has observed:

> The automatic, 30-month stay is a collateral injury the defendant's mere use of legal process invariably inflicts. And though the stay ends if a court holds the defendant's patent is invalid or has not been infringed, it does not otherwise depend on a suit's outcome. Thus, a plaintiff may be able to show a defendant was indifferent to the outcome of its infringement suit, and the automatic, 30-month stay was an anticompetitive weapon the defendant tried to wield.

Id. In other words, "[s]imply by suing, a patentee can delay the introduction of low-cost generic drugs to market and impede competition in the pharmaceutical industry." *Id.* at 340. Determining whether such anticompetitive conduct occurred is therefore a "delicate task" in the ANDA context. *Id.* at 361. The *AbbVie* court undertook that task with the benefit of a summary-judgment record. But this case is in a very different procedural posture.

Significant authority suggests that the applicability of the "sham" exception is "a question of fact for the jury." *Elysium*, 354 F. Supp. 3d at 336 (citing *In re Flonase Antitrust Litig.*, 795 F. Supp. 2d 300, 310 (E.D. Pa. 2011)); *see also Truck-Lite Co. v. Grote Indus., Inc.*, No. 18-CV-599, 2021 WL 8322467, at *12 (W.D.N.Y. Sept. 17, 2021) ("Determinations of whether a party's conduct is a genuine attempt to avail itself of the judicial process or is merely a sham is a question of fact that is inappropriate for a motion to dismiss."); *In re Outlaw Lab'y, LP Litig.*, No. 18-cv-840, 2019 WL 1205004, at *5 (S.D. Cal. Mar. 14, 2019) (noting that the "sham" determination is a question of fact and that, as a result, "courts rarely award *Noerr-Pennington*

immunity at the motion to dismiss stage" (quoting *Sonus Networks, Inc. v. Inventergy, Inc.*, No. C-15-0322, 2015 WL 4539814, at *2 (N.D. Cal. July 27, 2015))); *Takeda Pharm. Co. v. Zydus Pharms. (USA) Inc.*, 358 F. Supp. 3d 389, 394 (D.N.J. 2018) ("[D]istrict courts within this Circuit have routinely prohibited parties from invoking the protections of *Noerr-Pennington* at the dismissal stage of a case in the context of patent suits, at which time the factual record remains undeveloped and insufficient for the purpose of determining whether a 'sham litigation' has been filed.").[19]

Teva asserts that courts can decide *Noerr-Pennington* issues on a motion to dismiss when immunity does not depend on disputed facts. (Doc. 49 at 41.) Teva cites several cases in which courts dismissed antitrust claims at the Rule 12(b)(6) stage after determining that the defendant's action was not objectively baseless. (*Id.* at 41 n.11.) But each of those cases is distinguishable.

The plaintiff in *Apotex Inc. v. Acorda Therapeutics, Inc.* claimed that the defendant filed a sham citizen petition in violation of the Sherman Act. 823 F.3d 51, 59 (2d Cir. 2015). In support of its claim, the plaintiff alleged that the FDA approved the generic drug on the same day that it rejected the plaintiff's citizen petition. Taking notice of the FDA's recently issued "Guidance for Industry" that favored contemporaneous adjudications,[20] the Second Circuit ruled that the guidance undermined the inference "that when a citizen petition is denied simultaneously with the grant of an ANDA petition, the citizen petition was a sham and an anticompetitive weapon." *Id.* at 60. Absent any other facts from which a "sham" could plausibly be inferred, the

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[19] *See also* Esther H. Steinhauser, *Is Noerr-Pennington Immunity Still a Viable Defense Against Antitrust Claims Arising from Hatch-Waxman Litigation?*, 61 Food & Drug L. J. 679, 693 (2006) (asserting that recent decisions in Hatch-Waxman litigation show that "courts are less willing to allow antitrust charges to be dismissed on a defense of *Noerr-Pennington* protection").

[20] *Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act*, 2011 WL 2836582 (June 2011).

Second Circuit affirmed dismissal of the antitrust claim. *Id.* at 61–62. In contrast to *Apotex*, the allegedly anticompetitive conduct at issue for purposes of this analysis is not a citizen petition but a set of lawsuits regarding the 40 mg product. Determining whether the lawsuits were a sham is a "delicate task" that would be inappropriate on this relatively undeveloped record.

In *Bath Petroleum Storage, Inc. v. Market Hub Partners, L.P.*, the Second Circuit affirmed the Rule 12(b)(6) dismissal of antitrust claims under *Noerr-Pennington*, agreeing with the district court's findings that the defendants' interventions in a series of administrative proceedings were not objectively baseless. 229 F.3d 1135 (2d Cir. 2000) (summary order). But *Bath Petroleum* did not involve any claim of patent infringement. Moreover, the district court was able to rely on documents from the administrative proceedings to determine that none of the defendants' statements in those proceedings were misrepresentations.

Ruling on a Rule 12(b)(6) motion, the court in *AstraZeneca AB v. Mylan Laboratories, Inc.* found that the underlying patent litigation was not objectively baseless and concluded that the sham litigation exception did not apply. No. M-21-81, 2010 WL 2079722, at *4 (S.D.N.Y. May 19, 2010). The *AstraZeneca* court was able to make that determination, however, because it had previously ruled on summary judgment that there were genuine issues of fact as to whether the patents were infringed and because it had ruled after a bench trial that the patent-holder had proven two of three contested limitations of its claims were found in the competitor's product. *Id.* Here, in contrast, Teva's 40 mg infringement claims were not tested on summary judgment, and Teva did not prevail on any issues in the 40 mg litigation.

Finally, in *Marchon Eyewear, Inc. v. Tura LP*, No. 98 CV 1932, 2002 WL 31253199 (E.D.N.Y. Sept. 30, 2002), the court dismissed a sham-litigation counterclaim that alleged a series of patent-infringement suits brought for anti-competitive purposes because the

counterclaim rested on only two suits: the infringement claim in *Marchon* itself, plus a prior unsuccessful infringement claim in *CVI/Beta Ventures, Inc. v. Tura LP*, 905 F. Supp. 1171 (E.D.N.Y. 1995). The court reasoned that two lawsuits did not add up to a "series" or "pattern" of suits sufficient to overcome the *Noerr-Pennington* defense. The court did not analyze the "objectively baseless" prong that applies when the theory is that a single action was a sham.

In short, while it might be possible in some cases to confer *Noerr-Pennington* immunity at the Rule 12(b)(6) stage, this is not such a case. And at this stage of the litigation—given the "delicate task" of applying the sham-litigation standard in a case like this one—the court is not evaluating whether the parties have identified disputed facts. On this undeveloped record, the court cannot determine whether the 40 mg litigation was an objective "sham."

Teva suggests that the court should award *Noerr-Pennington* immunity at this stage of the case because the 40 mg infringement suit was vigorously litigated and included a seven-day bench trial. (Doc. 66 at 16.) The court rejects that suggestion. Some courts have indeed declined to find underlying patent litigation to be a "sham" where that litigation was "hard-fought and close." *AstraZeneca AB v. Mylan Lab'ys, Inc.*, No. M-21-81, 2010 WL 2079722, at *4 (S.D.N.Y. May 19, 2010) (granting Rule 12(b)(6) motion). Here, the court has no difficulty finding that the 40 mg infringement suit was hard-fought.

But none of the adjudicators in that litigation suggested that it was a close case. In fact, each of the adjudicators who considered the issue—the PTAB,[21] Judge Sleet, and a three-judge panel of the Federal Circuit—concluded that the claims were invalid as obvious. Judge Sleet

[21] Teva argues that the PTAB's unfavorable decision carries no weight, in part because the PTAB applies a standard "far less favorable to patentees than governs civil litigation." (Doc. 66 at 16.) But courts evaluating the applicability of the *Noerr-Pennington* defense consider PTAB action as part of their analysis. *See, e.g.*, *In re Xyrem (Sodium Oxybate) Antitrust Litig.*, 555 F. Supp. 3d 829, 881 (N.D. Cal. 2021).

made his findings by "clear and convincing evidence." Of course, whether a lawsuit was objectively baseless is different than whether the litigant's suit was ultimately successful. *See PRE*, 508 U.S. at 60 n.5 ("[W]hen the antitrust defendant has lost the underlying litigation, a court must resist the understandable temptation to engage in *post hoc* reasoning by concluding that an ultimately unsuccessful action must have been unreasonable or without foundation." (internal quotation marks omitted)). But the outcomes in all of the 40 mg litigations make *AstraZeneca* distinguishable.

ii. Serial-Petitioning Exception

In addition to the single-petition exception discussed above, the court also considers the serial-petitioning exception here. Regarding that variety of the sham exception, the court notes that the Third Circuit has, on at least one occasion, "declined to apply" the serial-petitioning exception "in the Hatch-Waxman context." *FTC v. AbbVie Inc.*, 976 F.3d 327, 361 (3d Cir. 2020) (citing *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 157–58 (3d Cir. 2017)). That is because the Hatch-Waxman Act "incentivizes brand-name drug manufacturers to promptly file patent infringement suits by rewarding them with a stay of up to 30 months if they do so." *Wellbutrin*, 868 F.3d at 157–58 (citing 21 U.S.C. § 355(j)(5)(B)(iii)). Courts are disinclined "to penalize a brand-name manufacturer whose 'litigiousness was a product of Hatch-Waxman.'" *Id.* at 158 (quoting *Kaiser Found. Health Plan, Inc. v. Abbott Lab'ys, Inc.*, 552 F.3d 1033, 1047 (9th Cir. 2009)). Adopting that logic, Teva argues that the serial-petitioning exception does not apply to Teva's Hatch-Waxman lawsuits on the 20 mg or 40 mg products.[22] (Doc. 49 at 43.)

[22] Those Hatch-Waxman lawsuits are: the consolidated GA 20 mg patent-infringement cases filed against Sandoz in 2008 and against Mylan in 2009 that ended with the Federal

To the extent that Teva argues that Hatch-Waxman lawsuits are categorically exempt from the serial-petitioning exception, the court rejects that contention. The court does not read *AbbVie* as adopting such a sweeping proposition. To the contrary, the *AbbVie* court remarked only that it had declined to apply the exception in a particular Hatch-Waxman case: *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class.* And the *Wellbutrin* decision analyzed the serial-petitioning exception at the summary judgment stage—not on a motion to dismiss, as here. Moreover, the *Wellbutrin* court affirmed the district court's rejection of the serial-petitioning exception by reasoning that there was no "serial" or "pattern" of petitioning at all, and then further reasoning that the design and intent of Hatch-Waxman made the serial-petitioning charge "particularly inapt." 868 F.3d at 157.

This court interprets that analysis to mean that the design and intent of Hatch-Waxman bolstered the conclusion that the serial-petitioning exception did not apply *in that case*, not that Hatch-Waxman lawsuits are categorically exempt from the serial-petitioning exception.[23] And even if the Third Circuit has adopted a categorical exemption from the serial-petitioning exception for Hatch-Waxman cases, this court would respectfully decline to adopt that theory. The court has found no case from within the Second Circuit that endorses such a categorical exemption.

Circuit's decision in *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1338 (Fed. Cir. 2015), and the consolidated GA 40 mg cases that were at issue in *In re: Copaxone Consolidated Cases.*, 906 F.3d 1013 (Fed. Cir. 2018).

[23] The court recognizes that at least one district court within the Third Circuit has interpreted *AbbVie* as holding that the serial-petitioning exception categorically "does not apply in the Hatch-Waxman context." *Louisiana Health Serv. & Indem. Co. v. Janssen Biotech, Inc.*, No. 19-cv-14146, 2021 WL 4988523, at *8 n.20 (D.N.J. Oct. 27, 2021).

Although Hatch-Waxman lawsuits are not categorically exempt from the serial-petitioning exception, several other issues concerning that exception remain. Defendants argue that there is no meaningful "series" of legal proceedings; that the non-Hatch-Waxman suits do not support the exception because they did not trigger a stay on the approval of any generic application; and that the serial-petitioning exception does not apply to Teva's citizen petitions "because the number of petitions is a byproduct of the FDA's procedures." (Doc. 49 at 43–44.) The court rejects those arguments for the reasons discussed next.

Defendants assert that Plaintiffs' "sham" argument is not directed to Teva's patent litigation regarding Copaxone 20 mg. Indeed, Teva achieved an entirely favorable result in the district court—*Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.*, 876 F. Supp. 2d 295, 419 (S.D.N.Y. 2012)—and preserved much of that victory on appeal. *See Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1338 (Fed. Cir. 2015). That patent litigation would not support the single-petition variety of the sham exception. *See PRE*, 508 U.S. at 60 n.5 ("A winning lawsuit is by definition a reasonable effort at petitioning for redress and therefore not a sham."). Plaintiffs do contend, however, that Teva's lawsuits regarding Copaxone 20 mg "bolsters the case for application of the serial litigation exception." (Doc. 58 at 34.)

The court agrees that it can consider the Copaxone 20 mg litigation as part of the "flexible" and "holistic" review that applies for the serial-petitioning exception. *Wellbutrin*, 868 F.3d at 157. The 20 mg litigation should be considered as part of the review of Defendants' "filing success—i.e., win-loss percentage." *Id.* The 20 mg litigation fits largely within the "win" column for Teva. But it must also be considered alongside Teva's undisputed losses in the district court and in the Federal Circuit in the consolidated Copaxone 40 mg cases. *See In re*

Copaxone Consol. Cases, No. 14-1171, 2017 WL 401943 (D. Del. Jan. 30, 2017), *aff'd* 906 F.3d 1013 (Fed. Cir. 2018).

Defendants argue that the *non*-Hatch-Waxman patent lawsuits cited in the complaint do not support the serial-petitioning exception because, according to Defendants, the complaint lacks any allegations that those suits were brought under a policy of starting legal proceedings without regard to the merits. (Doc. 49 at 43.) Defendants correctly recite the applicable standard for the serial-petitioning exception; as noted above, the inquiry is "whether the legal challenges 'are brought pursuant to a policy of starting legal proceedings without regard to the merits and for the purpose of injuring a market rival.'" *Primetime 24*, 219 F.3d at 101 (quoting *USS-POSCO*, 31 F.3d at 811). And Defendants may be correct that the non-Hatch-Waxman lawsuits did not trigger a stay on the approval of any generic application. But under the holistic review that applies here, these other lawsuits could plausibly constitute "circumstantial evidence of [Defendants'] subjective motivations." *Wellbutrin*, 868 F.3d at 157.

This is true notwithstanding the fact that the non-Hatch-Waxman suits were filed against different defendants and, in Teva's words, were "temporally and topically dispersed." (Doc. 49 at 44.) The court agrees that, where—as here—drug manufacturers face multiple generic-drug applications, it would be unreasonable to expect the manufacturers "to initiate litigation against only some of the generic-drug applications they claim are infringing their patents." *Twin City Bakery Workers & Welfare Fund v. Astra Aktiebolag*, 207 F. Supp. 2d 221, 224 n.2 (S.D.N.Y. 2002). Still, the non-Hatch-Waxman suits all involved GA patents, and even if they are effectively a single litigation, they can be considered together with the Hatch-Waxman lawsuits discussed above and with the citizen petitions, which the court considers next.

In addition to the patent litigation, the court considers Teva's citizen petitions. Defendants do not dispute that, between February 2008 and March 2015, Teva filed the eight unsuccessful citizen petitions described above. But Teva asserts that the serial-petitioning exception does not apply to those petitions "because the number of petitions filed is a byproduct of the FDA's procedures" and that "[a]s a matter of substance, Teva filed essentially one petition, which the FDA ruled on once." (Doc. 49 at 44.)

Plaintiffs oppose Teva's argument on this point, arguing that: (1) "Teva recycled essentially the same petition repeatedly"; (2) "although the FDA told Teva that it would not review its citizen petitions prior to ruling on the ANDA, Teva waited until May 2014, just before its patents ran out, to file suit and enjoin ANDA approval based on the issues raised in its petitions"; and (3) "when (as promised) the FDA addressed the issues raised by Teva in a denial issued concurrent with its approval of Sandoz's ANDA for 20 mg GA, Teva did not appeal." (Doc. 58 at 33.) Plaintiffs adopt the view expressed in one law review article that Teva's multiple petitions constitute "a particularly glaring example of a company's aggressive use of the citizen petition process." Michael A. Carrier & Carl Minniti, *Citizen Petitions: Long, Late-Filed, and At-Last Denied*, 66 Am. U. L. Rev. 305, 345 (2016).

Teva replies that "Plaintiffs never explain what Teva should have done differently to protect its rights before the FDA." (Doc. 66 at 18.) Teva asserts that Plaintiffs' other points are "self-contradictory." (*Id.*) Regarding Plaintiffs' claim that Teva waited until May 2014 to file suit against the FDA, Teva asserts that the court in that suit dismissed the action on ripeness grounds because the suit was filed before generic approval. *See Sebelius*, No. 14-cv-786 (D.D.C. May 14, 2014), ECF No. 36. Regarding Plaintiffs' note that Teva did not appeal the FDA's April 2015 approval of Sandoz's ANDA for 20 mg Glatopa, Teva observes that any appeal

would have been subject to a highly deferential standard of review[24] and that, if Teva had challenged the approval, "Plaintiffs would object to that too." (Doc. 66 at 18.)

The general rule regarding the applicability of the single-petition sham exception applies with similar force to citizen petitions analyzed under the serial-petition variety. *See In re Restasis (Cyclosporine Ophthalmic Emulsion) Antitrust Litig.*, 333 F. Supp. 3d 135, 154–55 (E.D.N.Y. 2018) ("[W]hether a citizen petition is a sham is generally a question of fact for the jury."). Whether a petition was a "sham" is an issue "independent of patent law." *DDAVP*, 585 F.3d at 686. "Administrative petitions, while less susceptible than lawsuits to the sham exception, still carry the potential for antitrust liability." *Id.*

The parties dispute whether Teva needed to file multiple citizen petitions to protect its rights. Plaintiffs assert that Teva "does not identify any FDA rule" requiring multiple petitions. (Doc. 58 at 33.) But Teva does not rely on an administrative rule; instead, Teva asserts that "the multiplicity of petitions was an artifact of FDA *policy and procedures*" (Doc. 66 at 18 (emphasis added))—namely, the policy appearing in the FDA guidance document cited above: *Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act*, 2011 WL 2836582 (June 2011) [hereinafter "FDA 505(q) Guidance"].

In that guidance document, the FDA acknowledged its legal obligation to respond to citizen petitions within 180 days of submission[25] and its simultaneous obligation to review applications such as ANDAs. The agency reasoned:

> If we were to respond substantively to a petitioner's request regarding the approvability of a certain aspect of a pending application before we have taken a final action on the approvability of the application as a whole, such response could

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[24] *See* 5 U.S.C. § 706(2).

[25] The deadline has since been shortened to 150 days. 21 U.S.C. § 355(q)(1)(F).

> interfere with the statutory and regulatory scheme governing the review of applications and related procedural rights of applicants.

FDA 505(q) Guidance, 2011 WL 2836582, at *12. The agency concluded that no "substantive final Agency decision" on a citizen petition was required within 180 days "when a final decision on the approvability of the [ANDA] as a whole has not yet been made and when to render such a decision could deprive an applicant of procedural rights established by statute and regulations." *Id.* The FDA stated that "[i]n such a situation, we would expect to deny a petition without comment on the substantive approval issue." *Id.* The FDA did just that for each of the relevant citizen petitions that Teva filed between February 2008 and July 2014 (with the exception of the petition that Teva withdrew).

The court understands from the argument at the July 14, 2023 hearing that the right Teva sought to protect by filing serial citizen petitions was the right to challenge the agency decision in court. In Teva's view, it needed to have a "live citizen petition" pending before the FDA at the time the FDA ruled on Sandoz's ANDA in order to ensure that Teva had exhausted its administrative remedies—a requirement for any subsequent court challenge. (Doc. 75 at 34–35.) But as Teva observes in its reply brief, Teva had no way to know when the FDA would rule on the pending ANDA. (Doc. 66 at 18.) Thus, according to Teva, it refiled its citizen petitions to ensure that it satisfied the exhaustion requirement and that it had an avenue available to challenge the agency decision.

But Teva cites no authority for the proposition that a "live" citizen petition is required to satisfy any exhaustion requirement that might apply to an effort to challenge the FDA's decision. In any case, if Teva sought to maintain a "live" citizen petition at all times until the FDA's ruling on Sandoz's ANDA, the record indicates that Teva's serial petitions failed to do so. There were

large gaps of time during which Sandoz's ANDA was pending but during which Teva had no "live" citizen petition:

Petition No.	Filed	Days Since Denial of Prior Petition	Denied (or Withdrawn)
1	09/26/2008	--	03/25/2009
2	11/13/2009	233	05/11/2010
3	12/10/2010	213	06/08/2011
4	06/04/2012	362	11/12/2012
5	09/12/2013	304	01/03/2014 (withdrawn)
6	12/05/2013	--	05/02/2014
7	07/02/2014	61	11/26/2014
8	03/31/2015	125	04/16/2015

(*See* Doc. 1 ¶ 89 n.47 (filing dates); *id.* ¶ 91 n.49 (denial/withdrawal dates).) Of course, Teva required some time to prepare and file each petition. But if Teva's motivation was to preserve an avenue to judicial review by having a "live" petition, it presumably could have prepared each subsequent petition in advance, rather than risk the possibility that the FDA might rule on the ANDA during one of the hundreds of days that Teva had no pending citizen petition. Teva may have other explanations, but at the present stage of this case, the court cannot conclude that the serial-petition exception is inapplicable.

b. Causation

Having concluded that Teva is not entitled to *Noerr-Pennington* immunity at this stage of the case, the court turns to Teva's causation argument—i.e., Teva's contention that its petitions and lawsuits did not delay FDA approval of Sandoz's or Mylan's ANDAs. (Doc. 49 at 44.) "Causation in fact is . . . a necessary element of any claim for relief . . . ." *In re Actos End-Payor Antitrust Litig.*, 848 F.3d 89, 97 (2d Cir. 2017) (quoting *Argus Inc. v. Eastman Kodak Co.*, 801 F.2d 38, 41 (2d Cir. 1986)). "An antitrust plaintiff must show that a defendant's anticompetitive act was a 'material' and 'but-for' cause of plaintiff's injury, although not necessarily the sole cause." *Id.* "[A] plaintiff need not exhaust all possible alternative sources of

injury in fulfilling his burden of proving compensable injury." *Id.* (quoting *Zenith Radio Corp. v. Hazeltine Rsch., Inc.*, 395 U.S. 100, 114 n.9 (1969)).

As noted above, Plaintiffs allege that Teva abused patent litigation and the FDA's citizen petition process "to artificially prolong Copaxone's patent exclusivity and block lower-cost generics from entering the market." (Doc. 1 ¶ 8.) Teva asserts that by the time that Sandoz's 20 mg ANDA was approved in April 2015, "there had been no litigation-based barrier to FDA approval for nearly a year." (Doc. 49 at 45.) Teva further contends that, at most, the Complaint alleges that the FDA rejected Teva's final citizen petition on the same day that it approved Sandoz's ANDA, but that the Second Circuit has held that the FDA 505(q) Guidance document undermines any inference of anticompetitive delay that might be asserted "when a citizen petition is denied simultaneously with the grant of an ANDA petition." *Apotex*, 823 F.3d at 60. And Teva maintains that 21 U.S.C. § 355(q)(1)(A) prohibits the FDA from delaying generic approval due to a pending citizen petition.

Similarly, Teva argues that the Complaint fails to plausibly allege that Teva's lawsuits or petitions delayed approval of Mylan's 20 mg and 40 mg ANDAs or Sandoz's 40 mg ANDA. (Doc. 49 at 46.) According to Teva, its citizen petitions could not have caused any delay because the last petition was submitted and denied in 2015 and thus "had no conceivable bearing on the timing of FDA approval of Mylan's ANDAs in October 2017." (*Id.* at 46.) Teva further asserts that the lawsuit on the 20 mg product ended long before Mylan's approval, and that Teva's lawsuit on the 40 mg product could not have delayed FDA approval "because Teva's 40 mg product was entitled to three years of marketing exclusivity, which barred the FDA from approving generic 40 mg until January 28, 2017." (*Id.*) Teva notes that the 30-month litigation

stay for the 40 mg lawsuit ended on January 30, 2017 and that the FDA did not approve Mylan's 20 mg or 40 mg ANDAs for another eight months. (*Id.*)

Plaintiffs contend that Teva's conduct did delay generic competition and that Teva's arguments to the contrary are unpersuasive. Plaintiffs assert that Teva's alleged sham litigation "is only part of its broader anticompetitive scheme." (Doc. 58 at 36.) Plaintiffs also argue that "Teva improperly asks the Court to draw inferences in its favor and assume that delays in FDA approvals and the lack of robust generic competition had nothing to do with its repeated lawsuits and administrative filings." (*Id.*) Plaintiffs maintain that the court cannot decide at this stage of the case that Teva's conduct did not delay generic entry; according to Plaintiffs, it is plausible that:

- Other generic manufacturers were deterred from entering the market earlier or at all because of the costs of defending against Teva's abusive litigation tactics.
- Approval of Sandoz's 20mg ANDA was delayed because the district court, at Teva's urging, mistakenly enjoined FDA approval until September 2015. As Teva concedes, the injunction was not shortened (to allow generic launch in May 2014) until late December 2013, Mot. 10, at which point it may have been too late for an overburdened FDA to adjust its timetable to decide the 20mg ANDA earlier.
- Teva's eight citizen petitions and related litigation consumed FDA resources, and the FDA's evaluation of Sandoz's 20mg ANDA was slowed by its evaluation of the multitude of purported "public health" issues raised in those petitions. Indeed, the FDA expressly stated that "it intended to consider the issues that [Teva] had raised [in its various petitions] *if and when FDA approved a generic version* of Copaxone."
- Mylan's pursuit of ANDAs was delayed by fending off four different lawsuits by Teva, including suits related to 40mg patents that Teva never should have obtained or asserted.

(Doc. 58 at 36–37 (alterations in original; footnote omitted).) In reply, Teva argues that Plaintiffs' reliance on the alleged "anticompetitive scheme" is misplaced because "no other

aspect of the purported 'scheme' is *even alleged* to have impacted the timing of FDA approval." (Doc. 66 at 19.) Teva further argues that Plaintiffs' other arguments are mere speculation.

i. FDA Approval of Sandoz's 20 mg ANDA

Teva correctly observes that the district court in the consolidated 20 mg Hatch-Waxman cases permitted generic launch in May 2014. Almost a full year passed from that time until the FDA approved Sandoz's 20 mg product in April 2015. Teva asserts that there was no "litigation-based barrier to FDA approval" during that time. (Doc. 49 at 45.) Plaintiffs interpret that as a concession that there was a one-year delay. (Doc. 58 at 36.) Plaintiffs further assert that the district court's July 2012 injunction—for which Teva advocated—was not modified to shorten the injunction period until December 2013, by which time, Plaintiffs argue, "it may have been too late for an overburdened FDA to adjust its timetable to decide the 20mg ANDA earlier." (*Id.*)

Teva's arguments do not persuade the court that Plaintiffs' allegations are implausible. It is true, of course, that there was no litigation-based barrier to FDA approval between May 2014 and April 2015. But it is reasonable to infer "that the stay resulting from the patent infringement litigation led the FDA to divert its resources away from" Sandoz's 20 mg ANDA. *Restasis*, 333 F. Supp. 3d at 159.

> The FDA may have prioritized reviewing applications for other generic drugs, because, even if tentative approval were granted to the ANDAs, a drug subject to a stay would not be able to enter the market for some time (possibly over a decade if the patent infringement suit were successful and the ANDA applicant had to wait until the patent expired).

Id. Such a diversion of resources could plausibly have occurred well before May 2014.

The court also rejects Teva's suggestion that the "only potentially relevant allegation" in the complaint regarding the citizen petitions is that the FDA rejected the final petition on the same day that it approved Sandoz's 20 mg product. (Doc. 49 at 45.) Plaintiffs are not required

to plead "a response to every potential argument" that Teva has raised. *Restasis*, 333 F. Supp. 3d at 159 n.14. In their briefing, Plaintiffs assert that the citizen petitions consumed FDA resources and slowed the FDA's evaluation of Sandoz's 20 mg ANDA. (Doc. 58 at 37.) As other courts have recognized, it is plausible to infer that the FDA "in practice does delay approval of generics while responding to citizen petitions" because "(1) [FDA] fears litigation if it grants an ANDA without fully addressing the citizen petition; and (2) [FDA] has limited resources, and responding to a citizen petition takes time away from the approval process." *Restasis*, 333 F. Supp. 3d at 158.

That inference is plausible notwithstanding the requirements of 21 U.S.C. § 355(q)(1)(A). *See id.* (citing cases); *see also Apotex*, 823 F.3d at 60 n.4 ("[I]t is not evident that [§ 355(q)(1)(A)] has curbed all abuses of the citizen petition process."). And the inference remains plausible even though the FDA had Teva's arguments "years in advance" of the ultimate approval (Doc. 66 at 20). *Cf. Restasis*, 333 F. Supp. 3d at 159 ("The FDA may have slowed or halted its review of ANDAs to address the citizen petitions and to account for the stay so that, even if the review is now moving along unobstructed, the ANDAs would have been approved months or even years ago had the petitions not been filed.").

ii. Mylan's ANDAs; Sandoz's 40 mg ANDA

The FDA did not approve Mylan's 20 mg ANDA (submitted in June 2009) until October 2017. FDA, ANDA 091646 Approval (Oct. 3, 2017), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/091646Orig1s000ltr.pdf [https://perma.cc/7MAN-AWJ6]. Teva notes that the October 2017 approval was more than two years after the April 2015 denial of Teva's last citizen petition, and even farther removed from the May 2014 expiration of the district court's injunction. (Doc. 49 at 46.) Thus, Teva asserts

that its lawsuits and petitions could not have delayed approval of Mylan's 20 mg product. The court disagrees; for the reasons explained above, it is plausible to infer that the ANDA would have been approved earlier if Teva had not filed the petitions and lawsuits.

The FDA did not approve Mylan's 40 mg ANDA (submitted in February 2014) until October 2017. FDA, ANDA 206936 Approval (Oct. 3, 2017), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/206936Orig1s000ltr.pdf [https://perma.cc/MG85-XHV4]. The FDA also did not approve Sandoz's 40 mg ANDA (submitted in February 2014) until February 2018. FDA, ANDA 206921 Approval (Feb. 12, 2018), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2018/206921Orig1s000ltr.pdf [https://perma.cc/4A84-66LQ]. Plaintiffs do not dispute Teva's observation that, as of January 2017, "no exclusivity or litigation stay blocked the FDA from approving" those 40 mg ANDAs. (Doc. 49 at 35.) But again, for the reasons explained above, it is plausible to infer that the ANDA would have been approved earlier if Teva had not filed the lawsuits alleging infringement of the patents for Copaxone 40 mg.

c. Time Bar

Teva's third argument regarding the effect of its petitions and lawsuits is based on the statute of limitations. (*See* Doc. 49 at 46.) Teva notes that the relevant lawsuits and citizen petitions were all filed more than seven years before Plaintiffs filed this federal suit in August 2022 and that any claim premised on Teva's litigation or petitioning conduct is time-barred under the Clayton Act's four-year limitations period at 15 U.S.C. § 15b and under the various state laws, which have limitations periods of six years or fewer. (*Id.* at 46–47.)

The court discusses the state statutes of limitations below. For purposes of the discussion here regarding the timeliness of the federal claim in Count IV, the court observes that Plaintiffs

have argued that Count IV seeks "only equitable relief pursuant to 15 U.S.C. § 26, to which the Clayton Act's statute of limitations does not apply." (Doc. 58 at 79 n.46.) Teva's reply memorandum does not respond to that point. The court agrees with Plaintiffs that the limitations provisions of 15 U.S.C. § 15b do not apply to claims brought under 15 U.S.C. § 26. *See Rite Aid Corp. v. Am. Express Travel Related Servs. Co.*, 708 F. Supp. 2d 257, 272 (E.D.N.Y. 2010) ("By its terms, the Clayton Act's four-year statute of limitations, 15 U.S.C. § 15b, does not apply to claims for equitable relief under section 16 of the Clayton Act, 15 U.S.C. § 26."), *abrogated on other grounds by U.S. Airways, Inc. v. Sabre Holdings Corp.*, 938 F.3d 43 (2d Cir. 2019); *see also Argus Inc. v. Eastman Kodak Co.*, 552 F. Supp. 589, 599 (S.D.N.Y. 1982) ("The relevant statute of limitations set forth at section 4B of the Clayton Act does not by its terms apply to claims for equitable relief pursuant to section 16 of the Clayton Act.").

Even though § 15b's limitations period does not apply to the § 26 claim in Count IV, courts in this circuit have held that a four-year period of laches applies to such claims. *Rite Aid*, 708 F. Supp. 2d at 272; *Argus*, 552 F. Supp at 600 ("[T]he equitable claims pursuant to section 16 of the Clayton Act are not time-barred unless plaintiffs are guilty of laches under the standard set forth above."). But Teva has offered no argument or analysis of the applicable laches doctrine. The court therefore declines to reach that issue insofar as it might apply to the claims in Count IV.

2. Alleged Conduct to Limit Generic Uptake

The second category of alleged anticompetitive conduct in this case is Teva's alleged conduct to limit generic uptake. Teva asserts that Plaintiffs' allegations under this category "suffer from numerous flaws." (Doc. 49 at 27.) Teva argues that its introduction and promotion

of Copaxone 40 mg was not anticompetitive. (*Id.* at 47.) Teva further argues that its efforts to compete with generic GA products do not support antitrust liability. (*Id.* at 52.)

a. Introduction and Promotion of Copaxone 40 mg

Teva's introduction and promotion of Copaxone 40 mg is analyzed under § 2 of the Sherman Act. *See* Herbert Hovenkamp et al., *An Analysis of Antitrust Principles Applied to Intellectual Property Law* § 15.03[B][1] ("Because product changes by pharmaceutical patent owners represent unilateral conduct, they are evaluated under section 2 of the Sherman Act."). To state a § 2 claim, Plaintiffs must establish: "(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *PepsiCo, Inc. v. Coca-Cola Co.*, 315 F.3d 101, 105 (2d Cir. 2002) (quoting *United States v. Grinnell Corp.*, 384 U.S. 563, 570–71 (1966)). For present purposes, Teva does not challenge Plaintiffs' contention that Teva maintained monopoly power before entry of generic 20 mg and 40 mg GA. (Doc. 49 at 52 n.18.)

The court therefore focuses here on the second essential element of a § 2 claim: willful acquisition or maintenance of monopoly power. To determine whether a product change violates § 2 based on the rule-of-reason test articulated in *Standard Oil Co. v. United States*, 221 U.S. 1 (1911), the Second Circuit has endorsed the framework set forth in *United States v. Microsoft Corp.*, 253 F.3d 34, 65 (D.D.C. 2001) (en banc) (per curiam). *See New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 652 (2d Cir. 2015) [hereinafter *Namenda*]. Under that framework: "once a plaintiff establishes that a monopolist's conduct is anticompetitive or exclusionary, the monopolist may proffer 'nonpretextual' procompetitive justifications for its conduct. The plaintiff may then either rebut those justifications or demonstrate that the

anticompetitive harm outweighs the procompetitive benefit." *Namenda*, 253 F.3d at 652 (citations omitted).

Plaintiffs allege that Teva sought to acquire or maintain monopoly power by means of a "product hop" from Copaxone 20 mg to Copaxone 40 mg. (*See* Doc. 1 ¶ 157.) In the Hatch-Waxman context, product-hopping can be anticompetitive. *See* Alan Devlin, *Exclusionary Strategies in the Hatch-Waxman Context*, 2007 Mich. St. L. Rev. 631, 658 (2007) ("Product hopping would have little competitive significance as an exclusionary strategy outside the regulatory process. However, the unique framework put in place by the Hatch-Waxman Act—and in particular the FDA-approval process—facilitates a potentially powerful form of exclusion.").

Teva contends that its introduction and promotion of the 40 mg product was not anticompetitive for three reasons. First, Teva asserts that the complaint fails to allege a "hard switch." Second, Teva maintains that the complaint fails to allege any coercion absent such a "hard switch." Third, Teva argues that Plaintiffs' product-hop claim is untimely. (Doc. 49 at 48–52.) The court considers these arguments in turn.

i. "Hard Switch"

As noted above, "product hopping" is "conduct by a monopolist to perpetuate patent exclusivity through successive products." *Namenda*, 787 F.3d at 643. Plaintiffs allege that Teva engaged in a product hop via a multi-pronged campaign that included "coerc[ing] and induc[ing] doctors, pharmacies, and patients to switch from 20 mg Copaxone to 40 mg Copaxone before Glatopa or other 20 mg generics became available for purchase." (Doc. 1 ¶ 168.) Teva argues that Plaintiffs "cannot state an antitrust claim based on Teva's alleged market-shifting strategy because they do not allege that Teva engaged in a 'hard switch.'" (Doc. 49 at 48.)

The parties have different definitions of the phrase "hard switch." Teva adopts the view in *In re Asacol Antitrust Litigation* that a "hard switch" means "removing the original drug from the market entirely right before patent expiration to deprive potential generic manufacturers a prescription base for their generic version of the now-removed drug." 233 F. Supp. 3d 247, 256 (D. Mass. 2017) (citing *Namenda*). And Teva argues that the complaint fails to allege a "hard switch" because the original product—Copaxone 20 mg—"remains on the market and continues to be prescribed to this day." (Doc. 49 at 49.)

Plaintiffs do not dispute that Teva never withdrew the 20 mg product from the market. But Plaintiffs assert that the alleged product hop in this case harmed competition even though the original product was never withdrawn. (*See* Doc. 58 at 39.) Plaintiffs contend that a "hard switch" is the label that is applied when a company "coerces" patients to switch products, whereas a "soft switch" applies when a company permissibly "persuades" patients to switch. (*See id.*) And Plaintiffs maintain that the complaint plausibly alleges coercive conduct (and thus a "hard switch" as Plaintiffs define it). (*Id.*)

The *Namenda* case involved an Alzheimer's disease medication. The defendants' patents on one version of the drug, "Namenda IR," prohibited generic competitors from marketing a generic version until July 2015. *Namenda*, 787 F.3d at 647. The defendants brought "Namenda XR" to market in July 2013; the patent exclusivity period for that version does not expire until 2029. *Id.* The two Namenda versions have different strengths and dosage regimens: "Namenda IR involves two immediate-release tablets of 10mg each and Namenda XR involves one 28mg extended-release capsule." *Id.* Generic versions of Namenda IR were poised to enter the market in July 2015, but those generics were not "therapeutically equivalent" to

Namenda XR under FDA regulations; thus pharmacists generally could not substitute generic IR for Namenda XR. *Id.*

When the defendants brought Namenda XR to market in 2013, they adopted certain "product extension" strategies to convert patients from IR to XR. (*Id.* at 647–48.)

> Initially, Defendants sold both Namenda IR and XR but stopped actively marketing IR. During that time, they spent substantial sums of money promoting XR to doctors, caregivers, patients, and pharmacists. They also sold XR at a discounted rate, making it considerably less expensive than Namenda IR tablets, and issued rebates to health plans to ensure that patients did not have to pay higher co-payments for XR than for IR.

Id. at 648 (footnotes omitted). The parties and the Second Circuit described those product-extension strategies—implemented while IR was still on the market—as the "soft switch." *Id.*

But in early 2014 the defendants were "concerned that they would be unable to convert a significant percentage of Alzheimer's patients . . . from IR to XR prior to the entry of generic IR." *Id.* In February 2014, the defendants announced plans to discontinue the IR product. A disruption in XR production delayed the planned discontinuance, and then a September 2014 antitrust suit resulted in an agreement under which defendants provided "limited access" to the IR product via a mail-order-only pharmacy in cases where a doctor found that the IR product was "medically necessary." *Id.* The defendants estimated internally that less than 3% of current IR users would be able to obtain IR through the mail-order pharmacy; thus the defendants' actions "effectively withdrew Namenda IR from the market." *Id.* The parties and the Second Circuit described the defendants' efforts to withdraw Namenda IR from the market as the "hard switch." *Id.*

On appeal, the Second Circuit noted that "[a]s a general rule, courts are properly very skeptical about claims that competition has been harmed by a dominant firm's product design changes." *Id.* at 652 (quoting *Microsoft*, 253 F.3d at 65). But "product redesign is

anticompetitive when it coerces consumers and impedes competition." *Id.* The court recognized that "neither product withdrawal nor product improvement alone is anticompetitive." *Id.* at 653–54.

> But under [*Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263 (2d Cir. 1979)], when a monopolist *combines* product withdrawal with some other conduct, the overall effect of which is to coerce consumers rather than persuade them on the merits, and to impede competition, its actions are anticompetitive under the Sherman Act.

Id. (citations omitted). The court concluded that "Defendants' hard switch—the combination of introducing Namenda XR into the market and effectively withdrawing Namenda IR—forced Alzheimer's patients who depend on memantine therapy to switch to XR (to which generic IR is not therapeutically equivalent)" and that the "hard switch" would "likely impede generic competition by precluding generic substitution through state drug substitution laws." *Id.* at 654. The Second Circuit affirmed the district court's grant of a preliminary injunction barring the defendants from restricting access to the IR product before generic IR entry. *Id.* at 644.

The court concludes that a "product hop" by definition involves withdrawal of an "old" or "legacy" product. *See* Alan Devlin, *Exclusionary Strategies in the Hatch-Waxman Context*, 2007 Mich. St. L. Rev. 631, 657 (2007) (defining a product hop as involving "a patentee switching the formulation of its patented drug as soon as a generic potential competitor's ANDA is approved" and "withdraw[al]" of the previous brand-name drug and replacement with the "improved" product); *see also* Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application* § 708f (defining product hopping as the situation where "[a] firm *terminates its sale* of a patented pioneer pharmaceutical drug prior to patent expiry, switching its promotion and market efforts to a newer version of the drug that is typically under one or more secondary patents" (emphasis added)).

The *Asacol* decision illustrates this point. The plaintiffs in *Asacol* brought three counts, alleging that the defendants (1) "engaged in an anticompetitive scheme that included product hopping that constituted monopolization in violation of Section 2 of the Sherman Act"; (2) "attempted monopolization in violation of Section 2 of the Sherman Act"; and (3) engaged in a "product hop monopolization in violation of Section 2 of the Sherman Act." *Asacol*, 233 F. Supp. 3d at 253. The *Asacol* court ruled that the product-hop claim based on an alleged "hard switch" to Asacol HD was not plausible "because Asacol and Asacol HD were sold side-by-side." *Id.* at 267. The court went on to state that product withdrawal "undergirds a product-hopping claim" and held that the lack of a "hard switch" was "insufficient pleading as to Asacol HD for the product hop claim in Count III." *Id.* at 270. Thus the absence of any allegation in this case that Teva withdrew Copaxone 20 mg from the market means that Plaintiffs cannot have plausibly alleged a "product hop" as that term is defined.[26]

But this does not end the inquiry because a "hard switch" or "product hop" is not essential to Plaintiffs' Sherman Act claims. Indeed, the *Asacol* court specifically stated that "the lack of a hard switch does not preclude the use of the Asacol HD marketing strategy in considering whether the Defendants engaged in an overall anticompetitive scheme in Counts I

[26] The court recognizes that some definitions of product-hopping might not require withdrawal of the legacy product. *See, e.g.*, *In re Loestrin 24 Fe Antitrust Litig.*, 433 F. Supp. 3d 274, 328 (D.R.I. 2019) (describing a "hard switch" as only "[o]ne example" of conduct constituting a product hop); Lina Khan & Sandeep Vaheesan, *Market Power and Inequality: The Antitrust Counterrevolution and Its Discontents*, 11 Harv. L. & Pol'y Rev. 235, 253 (2017) ("To ensure that the product hop is successful, some branded drug makers have even withdrawn the old version from the market . . . ."). The *Namenda* decision itself does not state whether withdrawal of the old product is essential to "product hopping" and instead defines that phrase generally as "conduct by a monopolist to perpetuate patent exclusivity through successive products." *Namenda*, 787 F.3d at 643. The court applies the narrower definition of a "product hop" in this case but notes that the conclusion about potential Sherman Act liability in connection with Teva's introduction and promotion of its 40 mg product turns on the particular allegations in the complaint, not on the precise definition of the phrase "product hop."

and II." *Id.* at 270. Whereas the complaint in *Asacol* included a specific Sherman Act "product hop" claim that was vulnerable to dismissal, the Sherman Act count in this case is more like Count I in *Asacol*: an alleged anticompetitive scheme that allegedly included a "product hop." The decisions of other courts are in accord:

> Although *Namenda* did involve withdrawal of Namenda IR in order to drive consumers over to Namenda XR, that does not mean the free choice of consumers can be constrained only where the old product is withdrawn from the market. . . . This is not to say that withdrawal of an old product, or the continued availability of such, is of no relevance in a switching/product hopping case. The Court is simply noting here that withdrawal of an old product is not the only means of coercion.

In re HIV Antitrust Litig., No. 19-cv-02573, 2023 WL 3088218, at *8 (N.D. Cal. Feb. 17, 2023). The continued availability of Copaxone in the 20 mg formulation is not fatal to Plaintiffs' claim. The parties also disagree about whether Plaintiffs have plausibly alleged coercion. The court turns to that issue next.

ii. Coercion

Teva argues that the complaint in this case fails to plausibly allege coercion. (Doc. 49 at 50.) Plaintiffs maintain that the complaint includes allegations of coercion that are "more than sufficient at the pleading stage." (Doc. 58 at 41.) Although Plaintiffs do not allege that Teva ever withdrew its 20 mg product, Plaintiffs do allege—as described above—that Teva: (a) manipulated the prices of its Copaxone products; (b) pressured PBMs by withholding rebates on Copaxone 20 mg unless the PBMs made the 40 mg product available on their formularies; (c) colluded with PBMs on the "Copaxone conversion initiative"; (d) launched an "intense outreach campaign" targeting prescribing physicians; and (e) explored a plan to discontinue copay assistance for the 20 mg product. (*See id.* at 40–41.)

As noted above, "product redesign is anticompetitive when it coerces consumers and impedes competition." *Namenda*, 787 F.3d at 652. The Second Circuit puts "emphasis on

consumer coercion in evaluating a monopolist's product redesign." *Id.* at 652 n.23. And the *Namenda* court's interpretation of coercion is "in accord" with other circuit court decisions, including *Microsoft*. *Id.* The *Microsoft* court recognized the factually intensive nature of the coercion analysis:

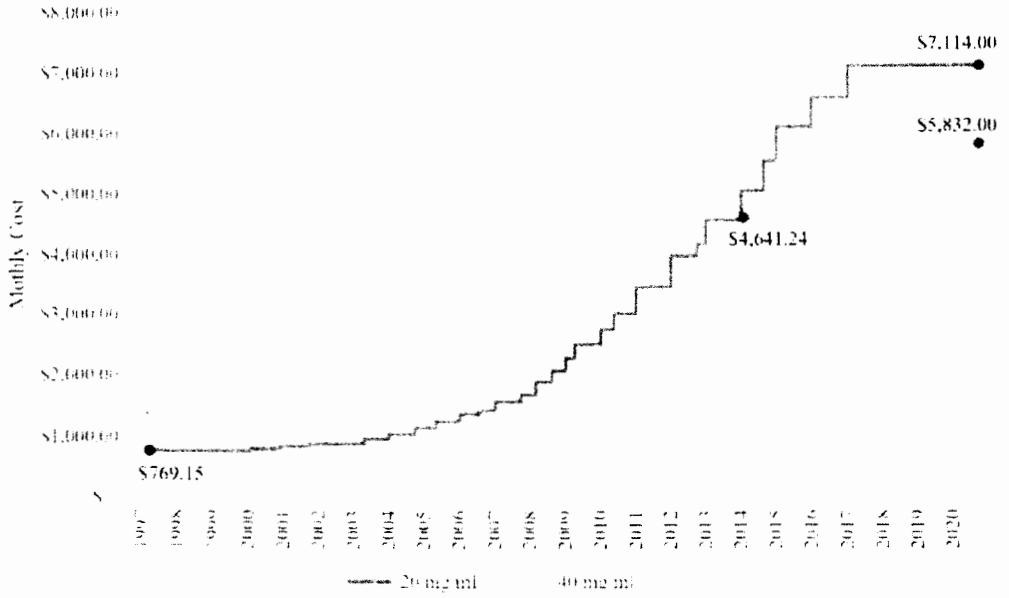
> Whether any particular act of a monopolist is exclusionary, rather than merely a form of vigorous competition, can be difficult to discern: the means of illicit exclusion, like the means of legitimate competition, are myriad. The challenge for an antitrust court lies in stating a general rule for distinguishing between exclusionary acts, which reduce social welfare, and competitive acts, which increase it.

Microsoft, 253 F.3d at 58. The *Namenda* case examines one set of circumstances but "*Namenda*-style coercion is not necessarily required." *In re Loestrin 24 Fe Antitrust Litig.*, 433 F. Supp. 3d 274, 331 (D.R.I. 2019). Whether Teva's alleged conduct "crosses the line from persuasion to coercion" requires careful consideration of all the circumstances. *Namenda*, 787 F.3d at 654.

Teva seeks to discount each of the five categories of alleged coercion upon which Plaintiffs rely. (*See* Doc. 49 at 50–52.) Regarding the alleged price manipulation (*see* Doc. 1 ¶ 169), Teva asserts that there is nothing inappropriate about offering discounts in an effort to win consumers over to a new product, and that Plaintiffs cannot prove coercion by arguing that the introductory price for Copaxone 40 mg was too low. (Doc. 49 at 50.) Plaintiffs insist that Teva manipulated pricing to coerce a change by "irrationally pricing its 40mg product lower than 20mg and then significantly *increasing the price of 20mg*." (Doc. 58 at 40.)

Plaintiffs concede that in *Namenda* the defendants' sale of the XR product at a discounted rate was part of the permissible "soft switch" in that case. (Doc. 58 at 40 n.20.) But Plaintiffs argue that, by *increasing* the price of the legacy product, Teva went beyond simply discounting the new product. Teva maintains that the complaint lacks any allegations that the price increase

for Copaxone 20 mg was out of step with "normal price increases" for that product. (Doc. 49 at 51.) Teva contends that the pricing data—as alleged in the complaint—suggest the opposite:



(Doc. 1 ¶ 59.)

One possible inference that could be drawn from inspection of this pricing timeline is that the price increases for Teva's 20 mg product after introduction of the 40 mg product are consistent with the prior price increases for Copaxone 20 mg. But at this stage of the case, the court must draw all reasonable inferences in Plaintiffs' favor. Here, the complaint alleges that Teva pitched the 40 mg product as an "upgrade" from the legacy product (*id.* ¶ 172) and as a "significant advancement" (*id.* ¶ 182), at least in part because the three-times weekly dosage was "more convenient to patients" (*id.* ¶ 179). Another reasonable inference, therefore, might be that the price for the "legacy" product should have dropped (or at least risen less steeply) once the "superior" product was available.

Regarding the alleged pressure on PBMs (Doc. 1 ¶ 170), Teva asserts that "Plaintiffs conflate improper coercion with legitimate (and successful) efforts to use price incentives *to*

increase customer choice by encouraging PBMs to offer *both* the 20 mg and 40 mg products in their formularies." (Doc. 49 at 51.) Plaintiffs argue that Teva did not just offer price discounts, but instead "*threatened to and did withhold* rebates *on a different product for which it had monopoly power* to force PBMs to add its new product to their formularies." (Doc. 58 at 40.)

On this issue, Plaintiffs do not dispute that Teva's conduct was designed to ensure that both the 20 mg and 40 mg products would be included in the PBMs' formularies. The presence of both products on the formularies arguably increased consumer choice as between Teva's Copaxone products. But the inquiry is whether Teva's conduct was exclusionary with respect to generic GA products. Plaintiffs' allegations on this issue support the inference that Teva used its monopoly power on its 20 mg product as one part of its alleged "multi-pronged campaign" (Doc. 1 ¶ 168) to switch patients to Copaxone 40 mg before widespread uptake of generic 20 mg GA products. Although the court in *Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394, 406 (3d Cir. 2016), stated that "the threat of a lost discount is a far cry from the anticompetitive conduct" that was held coercive in other cases, *Eisai* did not involve any attempt by the brand-name manufacturer to introduce a "new" version of its product. Here, the court considers Teva's alleged threat to withhold rebates in the overall context of Plaintiffs' switching theory.

Regarding the alleged "Copaxone conversion initiative" (Doc. 1 ¶ 171), Teva argues that "there is nothing anticompetitive about Teva promoting its product, or with specialty pharmacies doing the same." (Doc. 49 at 52.) Teva notes that the antitrust laws do not "prohibit[] market switching through sales persuasion short of false representations or fraud." *Walgreen Co. v. AstraZeneca Pharm. L.P.*, 534 F. Supp. 2d 146, 152 (D.D.C. 2008). And Teva maintains that Plaintiffs have not alleged that Teva made false representations to promote Copaxone 40 mg. (Doc. 49 at 52 n.17.)

Plaintiffs do not quarrel with the proposition that "sales persuasion" is permissible. But Plaintiffs do allege that Teva made false or misleading statements about Copaxone 40 mg, including Teva's statements at the launch in January 2014 that the new three-times-a-week product represented "a significant advancement for patients" and that it was an "innovation" that would address patient needs and ease patient burdens. (Doc. 1 ¶ 182.) According to the complaint, Teva made those assertions despite the fact that Teva's own personnel had stated that Copaxone 40 mg was not "a significant improvement in convenience" (Doc. 1 ¶ 179); that it had "no scientific rationale/value" (*id.*); and that it provided "[n]o major advantage on GA 20mg" (*id.* ¶ 181).

Teva maintains that there is an "obvious consumer benefit from substantially reducing the number of injections." (Doc. 49 at 50 n.16.) Judge Sleet made a similar finding in his 2017 decision. *See In re Copaxone Consolidated Cases*, 2017 WL 401943, at *23–24 (finding that Copaxone 40 mg "exhibits an advantage over the 20mg daily form" because the less frequent dosing is more tolerable for patients). Although Plaintiffs are entitled to the benefit of all reasonable inferences at this stage of the case, the court is not persuaded that Teva's statements at the 2014 product launch were false representations or fraudulent.

Plaintiffs also allege that Teva "directly targeted physicians with an intense outreach campaign through its sales force." (Doc. 1 ¶ 172.) Its salespeople contacted physicians to urge them to switch patients to the 40 mg formulation and to prescribe and recommend the Copaxone brand in place of a generic product. (*Id.*) Plaintiffs also allege that Teva considered a plan to discontinue copay assistance for the 20 mg dosage, thus coercing patients to switch to the 40 mg dosage. (*Id.* ¶ 173.)

The court is satisfied that considered together, the allegations about Teva's bare-knuckled defense of its monopoly position may be sufficient to support a factual determination at trial that patients were subjected to coercion in choosing between the brand and the generic versions of the drug. The combination of pricing the new 40 mg drug below the legacy 20 mg version, threatening to withhold rebates for the 20 mg version, and pressing prescribers to exclude new generic entrants from their orders is sufficient to constitute a claim of coercive conduct.

iii. Timeliness

Finally, Teva argues that Plaintiffs "cannot rely on Teva's alleged market-shifting efforts to support their federal or state antitrust claims that are subject to limitations periods of four years or fewer." (Doc. 49 at 52.) As noted above, the limitations provisions of 15 U.S.C. § 15b do not apply to claims brought under 15 U.S.C. § 26. Teva has offered no argument or analysis on the potential laches issue, and the court does not reach that issue here.

b. Efforts to Compete with Generic GA Products

Because the court concludes that the allegations concerning anti-competitive conduct in connection with the development and release of generic products provides a sufficient basis for denial of the motion to dismiss, the court does not reach the second claim that Teva's actions after Sandoz and Mylan entered the generic market also provide a basis for denial.

B. State-Law Claims

In addition to its challenge to Plaintiffs' Sherman Act claims, Teva challenges Plaintiffs' state-law claims.[27] Teva brings four categories of challenges to the state-law claims: (1) a set of challenges to the state antitrust claims; (2) a set of challenges to the state consumer-protection

[27] Some of the jurisdictions discussed below are not states but are United States districts or territories. For simplicity, the court refers to the claims in Counts I–III and V–VI as "state" law claims.

claims; (3) a set of challenges to the state unjust-enrichment claims; and (4) a statute-of-limitations challenge.[28] The court considers each category of challenges in turn.

1. State Antitrust Claims (Counts I–III)

Teva argues that Plaintiffs' state antitrust claims "are premised on the same allegations and suffer from the same deficiencies as their Sherman Act claims." (Doc. 49 at 68.) It is true that courts have dismissed state antitrust claims that are "premised on the identical actions that form the basis of the [dismissed] Sherman Act claims." *In re Suboxone (Buprenorphine Hydrochloride and Naloxone) Antitrust Litig.*, No. 13-MD-2445, 2017 WL 4642285, at *12 (E.D. Pa. Oct. 17, 2017). But for the reasons discussed above, the court concludes that Plaintiffs' Sherman Act claims survive Teva's Rule 12(b)(6) challenge. The court therefore turns to Teva's contention that Plaintiffs' claims "suffer from numerous state-law specific deficiencies." (Doc. 49 at 68.)[29]

a. *Illinois Brick*

As Teva observes, the "indirect purchaser" rule for federal antitrust cases "bars those who do not directly purchase a product from recovering antitrust damages." *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 662 (2d Cir. 2015) (citing *Illinois Brick Co. v. Illinois*, 431 U.S. 720, 745–46 (1977)); *see also Ne. Farm Sales & Serv., Inc. v. Krone NA, Inc.*,

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[28] Teva has provided a summary of the grounds upon which it relies for dismissal of Plaintiffs' state-law claims. (Doc. 49-2.)

[29] In a Notice of Supplemental Authority (Doc. 76), Plaintiffs cite *Mayor & City Council of Baltimore v. Merck Sharp & Dohme Corp.* for the proposition that "state antitrust laws are generally interpreted 'in parallel, if not identically' to the federal antitrust law." No. 23-828, 2023 WL 8018980, at *11 (E.D. Pa. Nov. 20, 2023) (quoting *In re Suboxone*, 2017 WL 4642285, at *11). But nothing about that general observation supports a simplistic conclusion that all of Plaintiffs' state-law antitrust claims are plausible merely because the Sherman Act claim is plausible.

No. 17-cv-72, 2018 WL 11469704, at *4 (D. Vt. Mar. 9, 2018) (recognizing that *Illinois Brick* "ruled out federal antitrust claims by indirect purchasers"). State legislatures retain the right to permit such recoveries under state antitrust laws. *Krone*, 2018 WL 11469704, at *4 (citing *California v. ARC Am. Corp.*, 490 U.S. 93 (1989)). But a state that "has not expressly passed *Illinois Brick* repealer legislation or interpreted its law in such a way as to override the rule of *Illinois Brick* is presumed to have decided to follow federal law, including the *Illinois Brick* limitation on indirect purchaser claims." *Miami Prods. & Chem. Co. v. Olin Corp.*, 546 F. Supp. 3d 223, 236 (W.D.N.Y. 2021) (quoting *In re Digit. Music Antitrust Litig.*, 812 F. Supp. 2d 390, 413 (S.D.N.Y. 2011)).

Teva contends that the *Illinois Brick* doctrine partly bars Plaintiffs' claims under Connecticut, Rhode Island, and Utah law. (Doc. 49 at 69.) Plaintiffs concede that they cannot recover antitrust damages under Connecticut law before October 1, 2017; under Rhode Island law before July 15, 2013; or under Utah law before May 1, 2006—the effective dates of those states' *Illinois Brick* repealer statutes. (Doc. 58 at 59 n.38.) The court will accordingly limit Plaintiffs' antitrust damages claims under those states' laws; those claims are barred prior to the respective dates listed above.

Teva also argues that Plaintiffs' claims for damages under Illinois and Puerto Rico antitrust law should be dismissed because those jurisdictions follow *Illinois Brick*. (Doc. 49 at 68.) Plaintiffs disagree, arguing that Illinois and Puerto Rico allow claims by indirect purchasers. (Doc. 58 at 59.) The court considers each jurisdiction in turn.

Illinois. The Illinois Antitrust Act ("IAA") states in pertinent part: "[N]o person shall be authorized to maintain a class action in any court of this State for indirect purchasers asserting claims under this Act, with the sole exception of this State's Attorney General, who may

maintain an action parens patriae as provided in this subsection." 740 ILCS § 10/7(2). Teva asserts that this statute adopts *Illinois Brick* and that the IAA's prohibition on indirect-purchaser class actions applies in federal court. (Doc. 49 at 69.) Plaintiffs maintain that the plain language of the Illinois statute limits the class-action prohibition to Illinois state courts, not federal courts. (Doc. 58 at 59–60.) Plaintiffs further argue that *Shady Grove Orthopedic Associates, P.A. v. Allstate Insurance Co.*, 559 U.S. 393 (2010), requires the same result. (*Id.* at 60.)

There appears to be no judicial consensus as to whether the IAA's prohibition on indirect-purchaser class actions applies in federal court.[30] Teva cites a number of cases—most from outside the Second Circuit—holding that the IAA bars indirect-purchaser actions in federal court.[31] Plaintiffs cite cases that reach the opposite conclusion.[32] The courts in the former category conclude that the IAA is "substantive" under *Shady Grove*, reasoning that Justice

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[30] *See Merck*, 2023 WL 8018980, at *13 ("No federal circuit has squarely addressed whether this rule bars class actions in federal court, and district courts are divided over the issue."); *In re Dealer Mgmt. Sys. Antitrust Litig.*, No. 18 C 864, 2023 WL 4305901, at *47 (N.D. Ill. June 29, 2023) (noting "conflicting district court opinions"); *In re Effexor Antitrust Litig.*, 357 F. Supp. 3d 363, 391 (D.N.J. 2018) ("District courts are divided on whether the [IAA] precludes indirect purchasers from filing class actions."); *Contant v. Bank of Am. Corp.*, No. 17 Civ. 3139, 2018 WL 5292126, at *11 (S.D.N.Y. Oct. 25, 2018) (same).

[31] *See, e.g.*, *Staley v. Gilead Scis., Inc.*, 446 F. Supp. 3d 578, 626 (N.D. Cal. 2020); *In re Lipitor Antitrust Litig.*, 336 F. Supp. 3d 395, 418 (D.N.J. 2018); *In re Opana ER Antitrust Litig.*, 162 F. Supp. 3d 704, 723 (N.D. Ill. 2016); *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, No. 14-md-02503, 2015 WL 5458570, at *17 (D. Mass. Sept. 16, 2015); *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 408–09 (D. Mass. 2013); *In re Digit. Music Antitrust Litig.*, 812 F. Supp. 2d 390, 416 (S.D.N.Y. 2011) ("Illinois' restrictions on indirect purchaser actions must be applied in federal court." (quoting *In re Wellbutrin XL Antitrust Litig.*, 756 F. Supp. 2d 670, 677 (E.D. Pa. 2010))).

[32] *See, e.g.*, *Contant v. Bank of Am. Corp.*, No. 17 Civ. 3139, 2018 WL 5292126, at *12 (S.D.N.Y. Oct. 25, 2018) ("[T]he IAA allows for class actions in federal court."); *In re Propranolol Antitrust Litig.*, 249 F. Supp. 3d 712, 728 (S.D.N.Y. 2017); *In re Aggrenox Antitrust Litig.*, No. 14-md-2516, 2016 WL 4204478, at *5 (D. Conn. Aug. 9, 2016). In their Notice of Supplemental Authority (Doc. 76), Plaintiffs also cite *Merck*, 2023 WL 8018980, at *13–14.

Stevens' concurrence in that case is controlling. Courts in the latter category conclude that the IAA is "procedural" under *Shady Grove*, and thus Fed. R. Civ. P. 23 imposes the only relevant class action requirements.

Before considering the *Shady Grove* issue, the court examines the "court of this State" language of 740 ILCS § 10/7(2). As it is worded, the statute's bar on class actions by indirect purchasers can be read as limited only to actions "in any court of this State"—i.e., any Illinois state court. Some courts have held or suggested that this is the correct interpretation of the IAA. *See Merck*, 2023 WL 8018980, at *14 ("[T]he plain language of the statute itself does not suggest a legislative intent to foreclose all private class actions, but merely those in Illinois state courts."); *Contant*, 2018 WL 5292126, at *12 ("[T]he statute, by its terms, does not apply in federal court . . . ."); *Propranolol*, 249 F. Supp. 3d at 728 ("It is not obvious that the formulaic expression 'in any court of this State' appearing in an Illinois statute applies to a federal court in [New York] . . . ." (alteration in original; quoting *Aggrenox*, 2016 WL 4204478, at *5))).

Teva's reply brief does not address this issue, and thus Teva has "arguably conceded the point." *State St. Glob. Advisors Tr. Co. v. Visbal*, No. 19-cv-1719, 2023 WL 4053170, at *29 n.17 (S.D.N.Y. June 16, 2023). Moreover, this court has given effect to statutory provisions that, by their terms, apply only to actions in state court. *See Wakefield v. Scott*, No. 17-cv-115, 2017 WL 11724172, at *3 (D. Vt. Aug. 15, 2017) (recognizing that 9 V.S.A. § 4506(a), which authorizes actions in Vermont Superior Court, constitutes consent to suit in state court but not federal court). The court adheres to that logic in this case and holds that the limitation in 740 ILCS § 10/7(2), by its own terms, does not apply to the federal court in Vermont.

The court is also not persuaded that *Shady Grove* requires dismissal of Plaintiffs' Illinois antitrust claims. The question in *Shady Grove* was whether N.Y. C.P.L.R. § 901(b)—which

prohibits class actions in suits seeking penalties or statutory minimum damages—"precludes a federal district court sitting in diversity from entertaining a class action under Federal Rule of Civil Procedure 23." *Shady Grove*, 559 U.S. at 396. As summarized by Judge Underhill in *Aggrenox*, the *Shady Grove* Court answered "no" and held "that Rule 23 applied in federal court to claims brought under New York law despite New York's general class action bar." *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 253 (D. Conn. 2015).

But as Judge Underhill observes: "It is difficult to isolate a holding in *Shady Grove* that is much broader than that, because the holding was announced by Justice Scalia in an opinion that garnered a majority only in part and a plurality in part. The fifth vote for the judgment was provided by Justice Stevens, who wrote a separate concurrence." *Id.* at 253–54. In his concurrence, Justice Stevens concluded that N.Y. C.P.L.R. § 901(b) is a procedural rule and "not part of New York's substantive law." *Shady Grove*, 559 U.S. at 416 (Stevens, J., concurring in part and concurring in judgment). At the same time, Justice Stevens wrote that "there are some state procedural rules that federal courts must apply in diversity cases because they function as a part of the State's definition of substantive rights and remedies." *Id.* at 416–17. Justice Stevens explained that in his view, a federal rule like Rule 23 "cannot govern a particular case in which the rule would displace a state law that is procedural in the ordinary use of the term but is so intertwined with a state right or remedy that it functions to define the scope of the state-created right." *Id.* at 423.

Federal courts considering the applicability of the IAA's prohibition on indirect-purchaser class actions differ over whether Justice Stevens' concurrence controls. The courts holding that the IAA bars indirect-purchaser actions in federal court rely on the *Marks* doctrine:

> When a fragmented Court decides a case and no single rationale explaining the result enjoys the assent of five Justices, the holding of the Court may be viewed as

> that position taken by those Members who concurred in the judgments on the narrowest grounds.

United States v. Alcan Aluminum Corp., 315 F.3d 179, 189 (2d Cir. 2003) (quoting *Marks v. United States*, 430 U.S. 188, 193 (1977)). Reasoning that Justice Sevens' concurrence represents the "narrowest grounds" for the *Shady Grove* decision, courts such as those that Teva cites have held that the IAA's restrictions on indirect purchaser actions are intertwined with Illinois substantive rights and remedies, and thus not governed by Rule 23. *E.g.*, *Staley v. Gilead Scis., Inc.*, 446 F. Supp. 3d 578, 624–25 (N.D. Cal. 2020) (quoting *United Food & Com. Workers Loc. 1776 & Participating Emps. Health & Welfare Fund v. Teikoku Pharma USA, Inc.*, 74 F. Supp. 3d 1052, 1084 (N.D. Cal. 2014)).

That reasoning is unpersuasive. Initially, it is not at all clear that Justice Stevens' concurrence is controlling. The *Marks* doctrine applies only where "one opinion can meaningfully be regarded as 'narrower' than another—only when one opinion is a logical subset of other, broader opinions." *Alcan*, 315 F.3d at 189 (quoting *King v. Palmer*, 950 F.2d 771, 781 (D.C. Cir. 1991) (en banc)). This court agrees with the observation in *Aggrenox* that Justice Stevens' *Shady Grove* concurrence "is 'narrower' than the position of the other Justices who made up the *Shady Grove* majority only in the sense that it would reject state procedural rules in fewer cases." *Aggrenox*, 2016 WL 4204478, at *5.

> It is not *logically* narrower, however, because it is not a logical subset of the opinion of the other Justices in the majority. Those Justices do not implicitly approve of its rationale for sometimes allowing state procedural rules to control—on the contrary, they explicitly reject that rationale—and it therefore does not represent the common denominator of the Court's reasoning.

Id. (emphasis added). Justice Stevens' *Shady Grove* concurrence, therefore, "is, in effect, *Marks*-doctrine dicta rather than *Marks*-doctrine holding." *Id.* at *6.

Teva has not provided any significant analysis on this particular issue, except to note that, even if not controlling, Justice Stevens' concurrence may be "the most persuasive guide." (Doc. 66 at 34 n.22 (quoting *Aggrenox*, 2016 WL 4204478, at *6).) But even applying the *Shady Grove* concurrence, the court finds that 740 ILCS § 10/7(2)—like N.Y. C.P.L.R. § 901(b)—is procedural, not substantive or "intertwined" with Illinois rights and remedies, and thus not applicable in federal court. As the *Contant* court observed, if N.Y. C.P.L.R. § 901(b) did not "'abridge, enlarge or modify any substantive right,' then the IAA, which applies exclusively to antitrust class actions, must also be procedural." *Contant*, 2018 WL 5292126, at *12 (quoting 28 U.S.C. § 2072(b)); *see also Merck*, 2023 WL 8018980, at *14 ("[A]t its core, this provision does not appear to be motivated by a desire to close off relief, or dramatically alter private plaintiffs' rights to bring claims under the state antitrust law."); *Aggrenox*, 2016 WL 4204478, at *6 ("[I]f New York's state-law bar is not a procedural rule that alters the scope of a substantive right or remedy, then the narrower scope of Illinois's state-law bar does not make it one that does."). The court recognizes that other district courts have come to a different conclusion but respectfully declines to follow those decisions here.

Puerto Rico. What *Aggrenox* grants as to Illinois law, it takes away as to Puerto Rico law. The court adopts the entirety of the *Aggrenox* court's analysis as to Puerto Rico antitrust law, where the parties in that case made essentially the same arguments that Plaintiffs and Teva make here:

> Puerto Rico has not passed an *Illinois Brick* repealer, and its territorial courts have apparently not directly addressed the issue, but its antitrust law is generally construed as essentially embodying the jurisprudence relevant to the parallel federal law. The defendants therefore urge the interpretation that *Illinois Brick* applies and bars indirect-purchaser actions, citing the persuasive authority of other district courts that have come to that conclusion. The indirect purchasers cite *Rivera–Muñiz v. Horizon Lines Inc.*, 737 F. Supp. 2d 57 (D.P.R. 2010), a federal district court case that came to the contrary conclusion on the basis that

> Puerto Rico liberally construes its antitrust laws, and citing for that proposition *Pressure Vessels of Puerto Rico, Inc. v. Empire Gas de Puerto Rico*, 137 D.P.R. 497, 1994 P.R.-Eng. 909, 547 (P.R. 1994). As the defendants point out, however, *Pressure Vessels* did not address indirect-purchaser standing or the rule of *Illinois Brick*. And though I agree with the indirect purchasers' contention that the courts of a particular jurisdiction can authoritatively interpret their laws as allowing antitrust recovery by indirect purchasers even in the absence of an express *Illinois Brick* repealer by the legislature, I cannot conclude that *Pressure Vessels* is such an authoritative statement. In the absence of a clear decision—by either the legislature or by the jurisdiction's own courts—to allow indirect-purchaser recovery, the antitrust laws of a state (or territory) are interpreted as presumptively consistent with federal law. I therefore conclude that Puerto Rico follows the rule of *Illinois Brick* and all indirect-purchaser claims under its antitrust law are dismissed.

Aggrenox, 94 F. Supp. 3d at 252 (cleaned up).

Plaintiffs cite a handful of cases that come to the opposite conclusion, including *In re Xyrem (Sodium Oxybate) Antitrust Litig.*, 555 F. Supp. 3d 829 (N.D. Cal. 2021). These cases appear to be the minority view, and the court respectfully declines to follow them. The *Xyrem* court found that *Pressure Vessels* "did address *Illinois Brick*" because "it did cite and criticize four United States Supreme Court cases that explicitly applied *Illinois Brick*." *Id.* at 886. This court is not persuaded that the *Pressure Vessels* court's citation to those Supreme Court cases is sufficient to make *Pressure Vessels* an authoritative statement on indirect-purchaser standing.

b. Intrastate Conduct or Effects

Teva contends that the antitrust laws of eight jurisdictions—Washington, D.C., Mississippi, New York, North Carolina, Oregon, Tennessee, West Virginia, and Wisconsin—"require the challenged conduct or effects to have occurred solely (or primarily) *within* the jurisdiction." (Doc. 49 at 71.) Teva further argues that the complaint refers to alleged "intrastate effects" in "conclusory, boilerplate allegations" that are insufficient to allege the requisite jurisdiction-specific conduct or effects. (*Id.*) Plaintiffs maintain that their allegations "depict how Teva's nationwide conduct traverses state lines and affects purchasers and prescribers in

each state." (Doc. 58 at 63.) In reply, Teva insists that "several jurisdictions reject such generalized allegations as inadequate." (Doc. 66 at 37.)

The court agrees with the *Loestrin* court and concludes that Plaintiffs "have sufficiently pled intrastate activity where they allege nationwide antitrust violations, the antitrust impact of which was felt within each state." *Loestrin*, 410 F. Supp. 3d at 375. This appears to be the "majority" view, *id.*, and this court concurs with the point made in *Aggrenox*: "[I]t is not obvious why the *intra* state effect of anticompetitive conduct would not be reached by the cited statutes merely because *inter* state conduct predominates." *Aggrenox*, 94 F. Supp. 3d at 253; *see also Merck*, 2023 WL 8018980, at *13 (concluding that plaintiff sufficiently alleged anticompetitive conduct occurring in intrastate commerce even though the alleged conduct primarily impacted interstate commerce). The court has considered the cases that Teva cites but finds them distinguishable or unpersuasive.

c. Citizenship (Utah Claim)

Teva argues that the Utah antitrust claim must be dismissed because none of the named plaintiffs are citizens or residents of Utah, as required for a claim under the Utah Antitrust Act. *See* Utah Code Ann. § 76-10-3109(1)(a) ("A person who is a citizen of this state or a resident of this state . . . may bring an action . . . ."). Plaintiffs maintain that the complaint alleges that "class members overpaid for Copaxone in every relevant jurisdiction." (Doc. 58 at 67.) Plaintiffs cite several cases in support, including *In re Generic Pharmaceuticals Pricing Antitrust Litigation*, 368 F. Supp. 3d 814 (E.D. Pa. 2019). The court in that case reasoned that "[a]llegations that members of the putative class presumably include Utah . . . citizens and residents are sufficient to overcome a motion to dismiss." *Id.* at 838 (quoting *Hosp. Auth. of*

Metro. Gov't of Nashville v. Momenta Pharms., Inc., 353 F. Supp. 3d 678, 696 (M.D. Tenn. 2018)).[33]

The cases that Plaintiffs cite appear to be the minority position, however. *See In re Effexor Antitrust Litig.*, 357 F. Supp. 3d 363, 393 (D.N.J. 2018) ("The majority of courts that have been presented with this statute require at least one Utah citizen or resident to be a named plaintiff."); *see also Miami Products*, 546 F. Supp. 3d at 247 (citing *Effexor* and adopting majority approach). This court finds the majority view persuasive. The court will dismiss the Utah antitrust claims that remain[34] without prejudice to repleading that includes a Utah citizen or resident as a named plaintiff.

d. Unilateral Conduct (California and Kansas Claims)

Teva notes that the relevant antitrust laws in California and Kansas prohibit concerted action but do not apply to unilateral conduct. *See* Cal. Bus. & Prof. Code § 16700; Kan. Stat. Ann. § 50-101 et seq. Teva asserts that the claims in Counts I and II under those states' antitrust laws must be dismissed to the extent that they rely upon or are premised on unilateral conduct. (Doc. 49 at 74.) Plaintiffs concede that "courts have dismissed allegations of sham litigation or misuse of the citizen petition process as unilateral under California and Kansas law." (Doc. 58 at 67.) But Plaintiffs request that the court "refrain from doing so at this juncture, as discovery may reveal evidence of concerted action with respect to this conduct." (*Id.* at 67–68.)

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[33] The court in *Merck* cited *Momenta* to conclude that class certification is "a more appropriate stage" to resolve the question of whether a Utah resident or citizen must be among the named plaintiffs when a class action includes claims under the Utah Antitrust Act. *Merck*, 2023 WL 8018980, at *14. This court elects to address the issue now.

[34] As noted above, Plaintiffs concede that they cannot recover antitrust damages under Utah law before May 1, 2006.

The court's role at the Rule 12(b)(6) stage is to evaluate the allegations in the pleadings. The plausibility of the claims in the pleadings does not depend on what might or might not be revealed in the discovery process. Here, the allegations in Counts I and II include some conduct that can—at present—be viewed only as "unilateral," including Teva's alleged sham litigation and alleged misuse of the citizen petition process. The court will grant Teva's request to dismiss the portions of Counts I and II that seek relief under California and Kansas antitrust law insofar as those claims are based on unilateral conduct. This ruling does not affect any claims under Counts I and II that seek relief under California and Kansas antitrust law for concerted action, and the court's conclusion here is without prejudice to an amended pleading if discovery reveals evidence of concerted action with respect to the alleged sham litigation or citizen petition process.

e. Vermont Antitrust Claims

Teva argues that Plaintiffs' Vermont antitrust claims should be dismissed for the same reasons that Teva asserts Plaintiffs' consumer-protection claims should be dismissed. (Doc. 49 at 76 n.31.) The court rejects Teva's arguments against the Vermont consumer-protection claims for the reasons discussed below.

2. State Consumer-Protection Claims (Count V)

Teva argues that there are "multiple flaws" with Plaintiffs' claims under the consumer-protection laws in California, Delaware, Florida, Massachusetts, New Hampshire, New York, and Vermont. (Doc. 49 at 74.) Plaintiffs maintain that Teva has offered only a "hodgepodge of state-specific arguments" that are all "unfounded." (Doc. 58 at 68.) The court considers Teva's arguments in turn.

a. *Illinois Brick* Bars the Massachusetts § 11 Claim

Count V includes a claim for violation of the Massachusetts Consumer Protection Act ("MCPA"). In particular, Count V invokes Mass. Gen. Laws ch. 93A, § 11, which supplies a cause of action to "[a]ny person who engages in the conduct of any trade or commerce." (*See* Doc. 1 ¶¶ 334, 338.) Teva argues that the § 11 claim must be dismissed because the *Illinois Brick* rule applies to such claims. (Doc. 49 at 75.) Plaintiffs do not dispute that *Illinois Brick* applies to § 11 claims but argue instead that their Massachusetts claim in Count V should be allowed to proceed under Mass. Gen. Laws ch. 93A, § 9, which supplies a cause of action to "[a]ny person" other than a person entitled to bring a § 11 claim. (*See* Doc. 58 at 70–71.)

The court will grant dismissal of Count V insofar as it is based upon Mass. Gen. Laws ch. 93A, § 11 because *Illinois Brick* bars that claim. *See Loestrin*, 410 F. Supp. 3d at 373 (*Illinois Brick* applies to § 11 claims). Regarding the possibility of a claim under § 9, the court recognizes that the federal pleading rules "do not countenance dismissal of a complaint for imperfect statement of the legal theory supporting the claim asserted." *Johnson v. City of Shelby*, 574 U.S. 10, 11 (2014); *see also Marbury Mgmt., Inc. v. Kohn*, 629 F.2d 705, 712 n.4 (2d Cir. 1980) ("Generally a complaint that gives full notice of the circumstances giving rise to the plaintiff's claim for relief need not also correctly plead the legal theory or theories and statutory basis supporting the claim."). Teva does not dispute those principles but urges the court to dismiss any potential § 9 claim because, notwithstanding BCBSVT's status as a nonprofit, BCBSVT is in Teva's view "motivated by business considerations." (Doc. 66 at 36 (quoting *Loestrin*, 410 F. Supp. 3d at 373).)

Plaintiffs do not address the *Loestrin* court's holding that the third-party payors in that case—even if some or all of which are non-profits—failed to plead a § 9 claim because they are

"motivated by business considerations." *Loestrin*, 410 F. Supp. 3d at 373. Instead, Plaintiffs rely upon *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 491 F. Supp. 2d 20 (D. Mass. 2007). The court in that case remarked that "[t]he dividing line between a claim under § 9 and a business claim under § 11 is as clear as mud" and went on to conclude that third-party payor Blue Cross/Blue Shield of Massachusetts "is a non-profit organization acting pursuant to its legislative mandate," that "the reimbursement for prescription drugs is a key part of its core mission," and that "[t]here is no evidence that BCBSMA profited from its reimbursement for those over-priced drugs during the non-time-barred portion of the class period." 491 F. Supp. 2d at 82 (footnotes omitted). Plaintiffs also cite *In re Lorazepam & Clorazepate Antitrust Litigation*, where the court held that BCBSMA was "not engaged in 'trade or commerce' for the purposes of barring it from bringing a Section 9 claim, as it is a charitable institution not engaged in trade or commerce when it undertakes activities in furtherance of its core mission." 295 F. Supp. 2d 30, 45 (D.D.C. 2003).

The court concludes that the best course on this issue is to decline to attempt to determine at this time whether BCBSVT is engaged in "trade or commerce" (and thus disqualified from bringing a § 9 claim). Making that determination is "fact intensive." *Lorazepam*, 295 F. Supp. 2d at 45. The court will undertake that inquiry if Plaintiffs seek to amend their complaint to assert a § 9 claim. At present, however, the court notes that Plaintiffs cannot properly amend their complaint via an opposition to a Rule 12(b)(6) motion. *See Cole v. Foxmar Inc.*, 387 F. Supp. 3d 370, 383 n.5 (D. Vt. 2019) (citing cases holding that a plaintiff cannot use its opposition to a dispositive motion to amend the complaint). The court will dismiss Count V insofar as it is based upon Mass. Gen. Laws ch. 93A, § 11, and will consider the fate of any § 9 claim at a later time.

b. "Consumer" Requirements (Vermont and New York Claims)

New York. The New York claim in Count V is brought under N.Y. Gen. Bus. Law §§ 349 (Deceptive Acts and Practices Unlawful) and 350 (False Advertising Unlawful). (Doc. 1 ¶ 324.) "To successfully assert a claim under either section, 'a plaintiff must allege that a defendant has engaged in (1) consumer-oriented conduct that is (2) materially misleading and that (3) plaintiff suffered injury as a result of the allegedly deceptive act or practice.'" *Orlander v. Staples, Inc.*, 802 F.3d 289, 300 (2d Cir. 2015) (quoting *Koch v. Acker, Merrall & Condit Co.*, 18 N.Y.3d 940, 944 N.Y.S.2d 452, 452, 967 N.E.2d 675 (2012)). Teva argues that the complaint in this case fails to plausibly allege the requisite "consumer-oriented conduct." (Doc. 49 at 75.)

The complaint includes an allegation that "[a]s payors, Plaintiffs are consumers in the relevant markets as purchasers of Copaxone." (Doc. 1 ¶ 268.) This allegation is incorporated into Count V. (*Id.* ¶ 297.) It is true that there is no allegation that Plaintiffs purchase Copaxone for their "personal, family or household use." *Sheth v. N.Y. Life Ins. Co.*, 273 A.D.2d 72, 709 N.Y.S.2d 74, 75 (1st Dep't 2000). But sections 349 and 350 do not require the plaintiff to be a "consumer." *See Securitron Magnalock Corp. v. Schnabolk*, 65 F.3d 256, 264 (2d Cir. 1995) ("The critical question . . . is whether the matter affects the public interest in New York, not whether the suit is brought by a consumer or a competitor."); *Himmelstein, McConnell, Gribben, Donoghue & Joseph, LLP v. Matthew Bender & Co.*, 171 N.E.3d 1192, 1197 (N.Y. 2021) (error to hold that allegedly deceptive conduct was not "consumer oriented" just because the product was "not directed at consumers at large for personal, family, or household use").

What is required for claims under §§ 349 and 350 is "consumer-oriented conduct." "A defendant engages in 'consumer-oriented' activity if [the company's] actions cause any 'consumer injury or harm to the public interest.'" *Anderson v. Unilever United States, Inc.*,

607 F. Supp. 3d 441, 451 (S.D.N.Y. 2022) (alteration in original) (quoting *New York v. Feldman*, 210 F. Supp. 2d 294, 301 (S.D.N.Y. 2002)). "This requirement is liberally construed, and may be satisfied by showing that the conduct at issue potentially affects similarly situated consumers." *Id.* (cleaned up).

According to the complaint, Teva's alleged "acts and practices were consumer-oriented in that they exerted an impact broadly on purchasers of prescription drugs." (Doc. 1 ¶ 325.) The court concludes that Plaintiffs' allegations are sufficient for present purposes. *See, e.g.*, *In re Effexor Antitrust Litig.*, 337 F. Supp. 3d 435, 466 (D.N.J. 2018) (rejecting argument that § 349 claims brought by end-payor purchasers of antidepressant drug should be dismissed for failure to allege consumer-oriented conduct).

The cases that Teva cites are distinguishable or unpersuasive. The court in *Black Radio Network, Inc. v. NYNEX Corp.* dismissed a § 349 claim, reasoning in part that "the fact that consumers were the ultimate end-users [does not] convert the transaction into a consumer transaction." 44 F. Supp. 2d 565, 583 (S.D.N.Y. 1999). That may be so, but the complaint in *Black Radio Network* lacked "any reference to harm to the public at large." *Id.* Plaintiffs' complaint in this case explicitly alleges harm to purchasers of prescription drugs. (Doc. 1 ¶ 325.)

The court in *In re Automotive Refinishing Paint Antitrust Litigation* stated that "when the alleged deceptive act occurs in a transaction between two companies, even when the result of the deception impacts on a consumer, it is not actionable under § 349." 515 F. Supp. 2d 544, 552 (E.D. Pa. 2007). The court agrees that an alleged deceptive act in a business-to-business transaction is *not necessarily* consumer-oriented, even if the result has some impact on a consumer. *See Himmelstein*, 171 N.E.3d at 1198 (consumer-oriented element would not be satisfied where a claim is based on "[p]rivate contract disputes, unique to the parties" (quoting

Oswego Laborers' Loc. 214 Pension Fund v. Marine Midland Bank, 647 N.E.2d 741, 744 (N.Y. 1995))). But to the extent that *Automotive Refinishing Paint* suggests that deceptive acts in transactions between two companies can never be consumer-oriented, the court respectfully disagrees because that would be an overly narrow interpretation of New York law. The focus remains on whether the conduct at issue has "a broader impact on consumers at large." *Himmelstein*, 171 N.E.3d at 1197 (quoting *Oswego*, 647 N.E.2d at 744).

Finally, Teva relies on *In re Wellbutrin XL Antitrust Litigation*, 260 F.R.D. 143 (E.D. Pa. 2009), for the proposition that "courts have held that third-party payors like Plaintiff cannot pursue relief under § 349." (Doc. 49 at 76.) But the *Wellbutrin* court did not analyze whether the conduct in that case was consumer-oriented. Instead, the court addressed the defense argument that indirect purchasers of an antidepressant lacked standing because the claims were "too remote from any allegedly illegal act." 260 F.R.D. at 164. Teva attempts to raise that separate issue in its reply brief. (Doc. 66 at 35–36 & n.25.) The court concludes that Teva's citation to *Wellbutrin* in its opening brief did not squarely raise the issue, and the court declines to consider it here. *See Conn. Invs. LLC v. KDP, LLC*, No. 20-cv-179, 2023 WL 6600000, at *12 (D. Vt. Mar. 13, 2023) ("Courts in the Second Circuit generally do not consider arguments raised for the first time in a reply brief.").

Vermont. The Vermont Consumer Protection Act ("VCPA") claim in Count V is brought under 9 V.S.A. § 2453(a) and seeks remedies under 9 V.S.A. § 2461. (Doc. 1 ¶¶ 301, 309.) Plaintiffs assert that they "and the Vermont Members of the CPA Subclass are 'consumers' within the meaning of Vt. Stat. Ann. tit. 9, § 2451a(1)." (Doc. 1 ¶ 299.)[35] Teva notes that only a "consumer" may bring suit under 9 V.S.A. § 2461(b) and argues that Plaintiffs are not

[35] The complaint includes a specific definition of the "CPA Subclass." (Doc. 1 ¶ 251.)

"consumers" because "the Complaint does not allege that Plaintiffs purchased Copaxone or its generic equivalent for *their* use." (Doc. 49 at 76.) Plaintiffs maintain that they are "consumers" as defined by 9 V.S.A. § 2451a(1) and that federal courts that have barred insurers from recovering under the VCPA have "[m]isread[] Vermont Supreme Court precedent." (Doc. 58 at 68.)

The Second Circuit has recently stated that the definition of "consumer" under the VCPA is "a threshold issue that controls whether a plaintiff is entitled to protection under the Act in the first place." *RSD Leasing, Inc. v. Navistar Int'l Corp.*, 81 F.4th 153, 158 (2d Cir. 2023). The VCPA defines "consumer" as follows:

> "Consumer" means any person who purchases, leases, contracts for, or otherwise agrees to pay consideration for goods or services not for resale in the ordinary course of the person's trade or business but for the person's use or benefit or the use or benefit of a member of the person's household, or in connection with the operation of the person's household or a farm whether or not the farm is conducted as a trade or business, or a person who purchases, leases, contracts for, or otherwise agrees to pay consideration for goods or services not for resale in the ordinary course of the person's trade or business but for the use or benefit of the person's business or in connection with the operation of the person's business.

9 V.S.A. § 2451a(1). Unfortunately for courts attempting to address this threshold issue, "several terms featured in that definition are not defined in the statute and are subject to multiple plausible and divergent interpretations" and there is "little guidance" from Vermont courts on the matter. *RSD Leasing*, 81 F.4th at 156.

Here, as in *RSD*, the relevant portion of § 2451a(1) provides that a "consumer" is a person who purchases goods "not for resale in the ordinary course of the person's trade or business but for the use or benefit of the person's business or in connection with the operation of the person's business."

> Within that passage is one clause (the "use/benefit/operation" clause) that charts three different paths to "consumer" status based on whether a person purchases goods and services: (1) "for the use" of a business; (2) "for the . . . benefit" of a

> business; and (3) "in connection with the operation of" a business. The same passage also charts a separate route for a purchaser to be *disqualified* from "consumer" status: a person who purchases goods or services "for resale in the ordinary course" of the purchaser's "trade or business."

RSD Leasing, 81 F.4th at 160 (citations omitted). Teva argues that the complaint fails to allege Plaintiffs' qualification as "consumers" (Doc. 49 at 76) and that Plaintiffs are disqualified under the "not for resale in the ordinary course" clause (Doc. 66 at 35).

The court begins with whether the complaint plausibly supports a conclusion that Plaintiffs qualify as consumers under any of the three statutory paths to "consumer" status. According to the complaint:

> BCBSVT purchases, pays for, and/or provides reimbursement for some or all of the purchase price of prescription drugs dispensed to members of its health plans. BCBSVT purchased, paid for, and/or provided reimbursement for some or all of the purchase price of Copaxone prescriptions dispensed to members of its plans. BCBSVT continues to purchase, pay for, and/or provide reimbursement for some or all of the purchase price for Copaxone prescriptions dispensed to members of its plans.

(Doc. 1 ¶ 24.) The complaint includes similar allegations as to TVHP. (*Id.* ¶ 25.)

Plaintiffs argue that they "contracted or otherwise agreed to pay for consideration for Copaxone needed by their members" and that "[t]his occurred 'in connection with the operation' of Plaintiffs' business" because "paying for their members' health care *is* their core function." (Doc. 58 at 68.)[36] The court agrees and concludes that, at this stage of the case, Plaintiffs have sufficiently alleged that they purchased Copaxone "in connection with the operation of" Plaintiffs' businesses. The August 2016 *Aggrenox* decision stated that the VCPA's definition of "consumer" only "allows businesses to sue as consumers with respect to the products that they

[36] Plaintiffs do not appear to rely on the other two statutory pathways for qualification as a "consumer." The court concludes that it is unnecessary at this time to decide whether Plaintiffs purchased Copaxone for the "use" or "benefit" of their business.

use as consumers." *Aggrenox*, 2016 WL 4204478, at *9. But that analysis does not appear to address the alternative path to consumer status for businesses that purchase products "in connection with the operation" of the business.[37] Nor is it consistent with this court's holding that the VCPA "reaches all violators, not just those who are direct sellers to the ultimate user of the product." *MyWebGrocer, Inc. v. Adlife Mktg. & Commc'ns Co.*, 383 F. Supp. 3d 307, 313 (D. Vt. 2019).

The decision in *Sergeants Benevolent Association Health & Welfare Fund v. Actavis, PLC* suggests a different rationale for concluding that the indirect pharmaceutical purchaser in that case was not a "consumer" under 9 V.S.A. § 2451a(1). The analysis in that case emphasized § 2451a(1)'s "not for resale in the ordinary course" clause. No. 15 Civ. 6549, 2018 WL 7197233, at *52 (S.D.N.Y. Dec. 26, 2018). That decision arguably indicates that indirect purchasers like Plaintiffs might be subject to the separate VCPA's statutory *disqualification* mechanism. But according to the complaint, at least some of Plaintiffs' Copaxone transactions were not purchases of Copaxone for "resale" but were reimbursements for the drug. The court cannot conclude at this early stage of the case that the statutory disqualification mechanism applies.

c. "Deception," "Reliance," and Fed. R. Civ. P. 9(b)

Teva asserts that the complaint "fails to plausibly allege that Teva engaged in deception, as required by several states' consumer-protection laws"; fails to include "the factual detail required by [Federal Rules of Civil Procedure] Rule 9(b)"; and also fails to "allege with factual

[37] Other courts have adopted the *Aggrenox* analysis on this point but have also not supplied any rationale for finding the "in connection with the operation" clause inapplicable. *See In re Restasis (Cyclosporine Ophthalmic Emulsion) Antitrust Litig.*, 355 F. Supp. 3d 145, 161 (E.D.N.Y. 2018); *see also Sergeants Benevolent Ass'n Health & Welfare Fund v. Actavis, PLC*, No. 15 Civ. 6549, 2018 WL 7197233, at *52 (S.D.N.Y. Dec. 26, 2018) (citing *Restasis*).

specificity that anyone relied on Teva's alleged misrepresentations." (Doc. 49 at 77–78.) Teva contends that these defects require dismissal of Plaintiffs' consumer-protection claims under the laws of California, Delaware, Florida, New Hampshire, New York, Massachusetts, and Vermont. (*Id.* at 78–80.)

Plaintiffs maintain that Teva's arguments fail for three reasons. First, Plaintiffs assert that Rule 9(b) does not apply to their consumer-protection claims because fraud is not a required element under any of the state consumer-protection acts and Plaintiffs' consumer-protection claims are based "on Teva's unfair and anticompetitive conduct, not on common-law fraud or fraud-based statutory claims like RICO." (Doc. 58 at 71.) On that point, Teva maintains that Plaintiffs cannot so simply distinguish "unfair and anticompetitive" conduct from "deception." (Doc. 66 at 37.) In Teva's view, "Plaintiffs base their state-law claims on alleged false statements and material misrepresentations to which Rule 9(b) applies." (*Id.*) Second, Plaintiffs argue that even if Rule 9(b) did apply, the complaint satisfies that rule's requirements. (Doc. 58 at 71.) Third, Plaintiffs contend that "Teva's state-specific arguments do not hold water." (*Id.* at 72.)

The court begins with the following observations regarding the requirements of Rule 9(b). The rule states in pertinent part: "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). "Under Rule 9(b)'s particularity requirement, the plaintiff must '(1) detail the statements (or omissions) that the plaintiff contends are fraudulent, (2) identify the speaker, (3) state where and when the statements (or omissions) were made, and (4) explain why the statements (or omissions) are fraudulent.'" *Olson v. Major League Baseball*, 29 F.4th 59, 71 (2d Cir. 2022) (quoting *Eternity Glob. Master Fund Ltd. v. Morgan Guar. Tr. Co. of N.Y.*, 375 F.3d 168, 187 (2d Cir. 2004)).

Rule 9(b) "is not limited to allegations styled or denominated as fraud or expressed in terms of the constituent elements of a fraud cause of action." *Rombach v. Chang*, 355 F.3d 164, 171 (2d Cir. 2004). Thus, even where fraud is not an element of a particular cause of action—as Plaintiffs claim is so for every state consumer-protection act—Rule 9(b) might still apply to that cause of action where the claim is "predicated on fraud." *Id.*; *see also Olson*, 29 F.4th at 71 ("Claims sounding in fraud must satisfy the heightened pleading standards of Federal Rule of Civil Procedure Rule 9(b)."). Here, the parties disagree as to whether Plaintiffs' state consumer-protection claims are predicated on fraud.

The court agrees that the complaint includes multiple allegations that are expressed in terms evocative of fraud. (*See, e.g.*, Doc. 1 ¶ 9 (alleging "deceptive practices to manipulate the individuals and entities that selected products"); *id.* ¶¶ 13, 249, 267, 277, 307, 319, 331, 341, 352 (alleging "false statements" or "material misrepresentations"); *id.* ¶¶ 234, 243, 303, 306, 308, 314, 318, 320, 326, 337, 340, 347, 360, 372 (misrepresentations, omissions, or concealment); *id.* ¶ 239 (alleging "false or misleading representations").) The complaint also specifically describes some of Teva's alleged conduct as fraudulent. (*See, e.g.*, Doc. 1 ¶¶ 234, 239, 246, 247, 250, 303, 304, 338, 374.) But the use of those terms does not necessarily mean that Plaintiffs' state consumer-protection claims are predicated on fraud. *See In re Pork Antitrust Litig.*, 495 F. Supp. 3d 753, 780 (D. Minn. 2020) (concluding that consumer-protection claims primarily involved anticompetitive behavior and were not subject to Rule 9(b) despite the complaint's use of the terms "deceptive," "fraudulent," "omissions," and "misrepresentations"); *In re Generic Pharms. Pricing Antitrust Litig.*, 368 F. Supp. 3d 814, 827, 846 (E.D. Pa. 2019) (concluding that, although plaintiffs alleged that defendants engaged in "unfair competition or unfair,

unconscionable, deceptive or fraudulent acts or practices," the consumer-protection claims "rest[ed] on Defendants' alleged unconscionable or deceptive conduct, not on fraud").

Here, as in *In re Pork Antitrust Litigation*, Plaintiffs' state consumer-protection claims are "not intertwined with any explicit claims of fraud." *In re Pork Antitrust Litig.*, 495 F. Supp. 3d at 780. In the court's view, the central allegations in the complaint are of unfair or anticompetitive conduct, not fraud. (*See, e.g.*, Doc. 1 ¶¶ 1, 7 (alleging an "anticompetitive scheme"); *id.* ¶¶ 9, 11, 16 (alleging "anticompetitive" and "unfair" practices); *see also id.* at 120 (seeking injunction against Teva's alleged "anticompetitive," "unfair," and "unconscionable" business practices).) The complaint in this case does not allege fraud as the underlying basis for the alleged antitrust and consumer-protection claims. *Cf. Lum v. Bank of Am.*, 361 F.3d 217, 228–29 (3d Cir. 2004) (complaint alleged antitrust conspiracy to fix the prime rate and identified "how the rate fixing was accomplished—through fraud"), *abrogation on other grounds recognized by In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 323 n.22 (3d Cir. 2010); *In re Potash Antitrust Litig.*, 667 F. Supp. 2d 907, 947 (N.D. Ill. 2009) (pleading that asserted consumer-protection claims was "peppered with references to fraud" such that the claims were "premised on fraudulent conduct"), *aff'd sub nom. Minn-Chem, Inc. v. Agrium, Inc.*, 683 F.3d 845 (7th Cir. 2012) (en banc).

For the reasons stated above, the court rejects Teva's blanket assertion that all of Plaintiffs' state consumer-protection claims should be dismissed for failure to comply with Rule 9(b)'s pleading requirements. The court therefore proceeds to consider the remaining issues as to each relevant jurisdiction.

California. Teva argues that Plaintiffs' complaint fails to plead "actual reliance" on any allegedly deceptive or misleading statements as required by California's Unfair Competition

Law ("UCL"), Cal. Bus. & Prof. Code § 17200. (Doc. 49 at 78.) Plaintiffs maintain that reliance is only required for claims grounded in fraud or deception and that Plaintiffs' claims are based on Teva's alleged "broad unfair and anticompetitive scheme, not from specific misrepresentations or deception alone." (Doc. 58 at 73.) Teva's reply does not respond to that point, and the court agrees with Plaintiffs that "[t]he unlawful-business-practices prong of the UCL has no reliance requirement." *In re Pork Antitrust Litig.*, 495 F. Supp. at 781. And as discussed above, Plaintiffs' UCL claim is premised on alleged unlawful or unfair business practices, not on fraudulent practices.

Teva also argues that Plaintiffs' claims under § 17200 should be dismissed "to the extent they are premised on flawed Cartwright Act or federal claims." (Doc. 49 at 74 n.28.) It is true that the court in *Jones v. Micron Technology Inc.* dismissed a § 17200 claim because "[a] UCL claim for unlawful behavior is predicated on a violation of a separate statute or common law regime" and because the court found that the plaintiffs' Sherman Act and Cartwright Act claims were insufficiently pled. 400 F. Supp. 3d 897, 923 (N.D. Cal. 2019). Here, however, the court concludes that Plaintiffs' Sherman Act claims are plausible. The court will not dismiss the § 17200 claims for lack of a plausible predicate violation.

Delaware. Teva's sole argument for dismissal of the claim under the Delaware Consumer Fraud Act is that the claim sounds in fraud and should be dismissed for failure to satisfy Rule 9(b). (Doc. 49 at 78.) The court rejects that argument for the reasons stated above.

Florida. Teva's sole argument for dismissal of the claim under the Florida Deceptive and Unfair Trade Practices Act is that the claim sounds in fraud and should be dismissed for failure to satisfy Rule 9(b). (*Id.* at 78–79.) The court rejects that argument for the reasons stated above. *See also Merck*, 2023 WL 8018980, at *20 ("Here, Plaintiff alleges that Merck's bundling

practices and discounts constitute anticompetitive conduct but does not allege that Merck engaged in fraud. I therefore find that Plaintiff's claim under the Florida consumer law does not implicate Rule 9(b) and I will not dismiss its FDUTPA claim on this basis.").

New Hampshire. Teva's sole argument for dismissal of the claim under the New Hampshire Consumer Protection Act is that the claim sounds in fraud and should be dismissed for failure to satisfy Rule 9(b). (*Id.* at 79.) The court rejects that argument for the reasons stated above.

New York. Teva argues that N.Y. Gen. Bus. Law §§ 349 and 350 require allegations of a "deceptive" act or practice "that is actually deceptive." (Doc. 49 at 79.) Teva cites *In re Lamictal Indirect Purchaser & Antitrust Consumer Litigation* for the proposition that "mere anticompetitive conduct alone will not suffice." 172 F. Supp. 3d 724, 752 (D.N.J. 2016) (quoting *Leider v. Ralfe*, 387 F. Supp. 2d 283, 295–96 (S.D.N.Y. 2005)). According to Teva, Plaintiffs' claims under §§ 349 and 350 are based on alleged misleading statements and deceptive conduct that is not alleged with the required particularity. (Doc. 49 at 80.)

Plaintiffs concede that § 349 outlaws only "[d]eceptive acts or practices in the conduct of any business, trade or commerce." N.Y. Gen. Bus. Law § 349(a). The statute lacks any explicit language targeting "unfair" methods of competition or "unlawful" business practices. But Plaintiffs maintain that "courts routinely deny motions to dismiss § 349 claims based on anticompetitive schemes." (Doc. 58 at 73 (citing cases).) Plaintiffs do not explain whether the courts in the cited cases denied the motions because the courts in those cases disagreed with the proposition that deception is required or because the alleged anticompetitive conduct in those cases was "deceptive in nature." *See Lamictal*, 172 F. Supp. 3d at 752 ("[A]nticompetitive conduct *can* violate § 349 if it is deceptive in nature.").

In any case, the court concludes that the complaint in this case plausibly alleges anticompetitive conduct that—while not *predicated* on fraud, *see supra*—is sufficiently "deceptive in nature" for purposes of a § 349 claim. As the *Lamictal* court explained, a claim of anticompetitive conduct under § 349 can be "deceptive in nature" if, for example, it includes allegations that the defendants made efforts to conceal their anticompetitive agreement, secretly agreed to raise prices, or entered into "secret" anticompetitive agreements. *Lamictal*, 172 F. Supp. 3d at 752–53 (citing cases). The complaint in this case includes allegations that, at all relevant times, "Teva took active steps to conceal its unlawful activities." (Doc. 1 ¶ 234.) The court accordingly rejects Teva's request to dismiss the New York consumer-protection claims for lack of "deception."

Massachusetts. Teva's sole argument for dismissal of the claim under the Massachusetts Consumer Protection Act is that the claim sounds in fraud and should be dismissed for failure to satisfy Rule 9(b). (Doc. 49 at 80.) The court rejects that argument for the reasons stated above.

Vermont. Finally, Teva notes that the VCPA prohibits "[u]nfair methods of competition in commerce and unfair or deceptive acts or practices in commerce," 9 V.S.A. § 2453(a), and argues that the complaint does not plausibly allege deception because there are no allegations that any of Teva's alleged misleading statements were targeted at Plaintiffs or affected their conduct. (Doc. 49 at 80.) Plaintiffs maintain that they do not need to allege reliance on any deceptive acts or practices because their VCPA claim is based on Teva's alleged "unfair" conduct. (Doc. 58 at 73.) That clarification moots the portion of Teva's motion that seeks dismissal of the VCPA claims "to the extent they rely on deception." (Doc. 49 at 80.)

d. Intrastate Nexus

Finally, Teva argues that Plaintiffs' consumer protection claims under the laws of six states fail "because those states' laws require intrastate conduct or, at least, a significant nexus to the state, which the Complaint fails to plead." (Doc. 49 at 81.) Plaintiffs maintain that Teva's argument fails "for the same basic reason as in the antitrust context: conduct (especially related to pharmaceutical pricing) that by its nature forces illegally inflated prices on purchasers everywhere, irrespective of state lines, creates sufficient impacts in and connections to any state in which it is reasonable to infer sales occurred." (Doc. 58 at 74.)

The court agrees with Plaintiffs on this point. The court's conclusions above regarding the required intrastate conduct or effects for purposes of the antitrust claims apply equally to the consumer-protection claims. Plaintiffs have pleaded nationwide conduct, the consumer-protection impact of which reaches every state. The court has considered the cases that Teva cites but finds them distinguishable or unpersuasive.

3. State Unjust-Enrichment Claims (Count VI)

Finally, Count VI of the complaint is a claim for unjust enrichment brought "under the common law of all U.S. states and territories." (Doc. 1 ¶ 380.) Teva argues that Count VI should be dismissed for two reasons. First, Teva argues that Count VI fails to provide fair notice under each jurisdiction's particular law. (Doc. 49 at 84.) Second, Teva maintains that the unjust-enrichment claims are an improper attempt to "end-run" flaws in Plaintiffs' other state claims. (*Id.* at 85.) The court considers these arguments in turn.

a. Rule 8's Requirements

Teva argues that Count VI should be dismissed as inadequate under Fed. R. Civ. P. 8 because it fails to "plead the elements of unjust enrichment on a jurisdiction-specific basis."

(Doc. 49 at 84.) Teva asserts that jurisdiction-specific pleading is necessary because the requirements for the cause of action are different depending on the jurisdiction, and some jurisdictions do not recognize an unjust-enrichment cause of action at all. (*Id.* at 84–85.) Plaintiffs maintain that unjust-enrichment claims have "essentially" the same elements in every jurisdiction and that the complaint includes sufficient factual content as to each element to state a plausible claim. (Doc. 58 at 76; *see also* Pls.' App'x A, Doc. 58-1 (compilation of unjust-enrichment elements for each of the 50 states).) Teva insists that Plaintiffs wrongly "oversimplif[y]" state laws and omit state-specific requirements. (Doc. 66 at 37.)

"Under Federal Rule of Civil Procedure 8(a)(2), a pleading must contain a 'short and plain statement of the claim showing that the pleader is entitled to relief.'" *Iqbal*, 556 U.S. at 677–78. Rule 8 does not require dismissal of a complaint "for imperfect statement of the legal theory supporting the claim asserted." *Quinones v. City of Binghamton*, 997 F.3d 461, 468 (2d Cir. 2021) (quoting *Johnson v. City of Shelby*, 574 U.S. 10, 11–12 (2014)); *see also Hatmaker v. Mem'l Med. Ctr.*, 619 F.3d 741, 743 (7th Cir. 2010) (Posner, J.) ("[P]laintiffs in federal courts are not required to plead legal theories."); *Jones v. Westchester County*, 182 F. Supp. 3d 134, 149 (S.D.N.Y. 2016) ("[T]he Rules do not require a plaintiff to plead the legal theory . . . underlying his claim . . . ." (quoting *Phillips v. Girdich*, 408 F.3d 124, 130 (2d Cir. 2005))). "To stave off threshold dismissal for want of an adequate statement of their claim, plaintiffs are required to do no more than state simply, concisely, and directly events that, they allege, entitle them to damages." *Quinones*, 997 F.3d at 468 (cleaned up). That requirement differs from an inquiry under Rule 12 as to whether the complaint crosses the "plausibility" threshold. *See Quinones*, 997 F.3d at 469.

Here, Teva faults Count VI for including "a scant eight paragraphs." (Doc. 49 at 84.) But the facts alleged in Count VI include all of the allegations in the preceding 378 paragraphs of the complaint. (*See* Doc. 1 ¶ 379.) In the court's view, the extensive allegations in the complaint are sufficient for Rule 8 purposes as a statement of the events that Plaintiffs allege entitle them to damages, at least on a generic unjust-enrichment theory. *See* Restatement (Third) of Restitution and Unjust Enrichment § 1 cmt. a ("Liability in restitution derives from the receipt of a benefit whose retention without payment would result in the unjust enrichment of the defendant at the expense of the claimant."); *see also In re Flonase Antitrust Litig.*, 692 F. Supp. 2d 524, 541 (E.D. Pa. 2010) ("[A]lmost all states at minimum require plaintiffs to allege that they conferred a benefit or enrichment upon defendant and that it would be inequitable or unjust for defendant to accept and retain the benefit.").

Assessing the *plausibility* of the unjust-enrichment claim in each U.S. state and territory may require more granular analysis. As other courts have observed, "[s]tate law requirements under unjust enrichment law vary widely." *Miami Products*, 546 F. Supp. 3d at 247 (quoting *In re Packaged Ice Antitrust Litig.*, 779 F. Supp. 2d 642, 667 (E.D. Mich. 2011)); *see also Digital Music*, 812 F. Supp. 2d at 411 ("[T]he requirements to plead unjust enrichment vary by state . . . ."). But the court respectfully declines to follow *Miami Products* insofar as that case held that the indirect-purchaser plaintiffs' unjust-enrichment claims under various state laws failed to comply with Rule 8. In this court's view, pinning such a dismissal on Rule 8 would effectively require the plaintiffs to plead legal theories.

Moreover, as a practical matter, dismissal on Rule 8 grounds would do little in this case. When the *Miami Products* court dismissed the unjust-enrichment claims, it also granted leave to file a motion to amend those claims, *id.* at 250, and the plaintiffs proceeded to file an amended

complaint with over 100 additional paragraphs of largely rote or repetitive allegations with state-by-state point headings. *See* Am. Consolidated Class Action Compl., *In re Caustic Soda Antitrust Litig.*, No. 19-cv-385 (W.D.N.Y. Aug. 23, 2021), ECF No. 335. It does not appear to this court that those changes to the pleadings in that case made any difference to the defendants' ability to defend against the claims or to the plausibility analysis that the district court ultimately performed. *See Miami Prods. & Chem. Co. v. Olin Corp.*, No. 19-CV-00385, 2022 WL 3701159 (W.D.N.Y. Aug. 26, 2022).

The court therefore rejects Teva's invitation to dismiss all of the unjust-enrichment claims on Rule 8 grounds. Teva's list of "[e]xamples" of a handful of requirements in selected jurisdictions (Doc. 49 at 85) demonstrates that Teva is fully capable of discerning the nature of the claims in Count VI and defending against those claims. If Plaintiffs have failed to allege facts that might be essential to a particular jurisdiction's law of unjust enrichment—or if that cause of action is unavailable in some jurisdictions—such shortcomings should be evaluated directly as a challenge to the legal cognizability of the claims, not as a challenge to the sufficiency of the pleading. *See generally Lopez v. Wright*, No. 05-CV-1568, 2007 WL 388919, at *2 (N.D.N.Y. Jan. 31, 2007) (noting that a Rule 12(b)(6) motion can be based either on "(1) a challenge to the 'sufficiency of the pleading' under Rule 8(a)(2); or (2) a challenge to the legal cognizability of the claim" (footnote omitted)).

b. *Illinois Brick* (Redux) and Adequate Remedy at Law

Teva's second argument against the claims in Count VI can be divided into two components. First, Teva asserts that "[f]or jurisdictions that follow *Illinois Brick*, dismissal of Plaintiffs' unjust enrichment claims is required because allowing such claims to go forward 'would circumvent the policy of choice' of the jurisdiction." (Doc. 49 at 86 (footnote omitted)

(quoting *Flonase*, 692 F. Supp. 2d at 542).) Second, Teva contends that "[i]n the remaining jurisdictions, unjust enrichment is still an inappropriate remedy because Plaintiffs can proceed under state antitrust and consumer-protection laws" and thus Plaintiffs have an adequate remedy at law. (*Id.*)

Plaintiffs assert that Teva's *Illinois Brick* argument miscasts Plaintiffs' claims. (Doc. 58 at 78.) They concede that they cannot bring "parasitic" unjust-enrichment claims premised on the laws of states that follow *Illinois Brick*. (*See id.*) Other courts have so held. *See Digital Music*, 812 F. Supp. 2d at 413 (dismissing "all parasitic claims premised on the state laws of states that follow *Illinois Brick*"). Plaintiffs maintain, however, that their unjust-enrichment claims are not "parasitic" but are instead "independent claims for Teva's price-gouging for critical medication necessary to a debilitating illness through a host of schemes that are not limited to conduct within the scope of what is traditionally viewed as 'anticompetitive' conduct." (Doc. 58 at 78.)

The court is not persuaded that Plaintiffs' characterization is correct. "'In contemporary United States common law, restitution based upon unjust enrichment takes at least two forms'; it may be 'autonomous' or 'parasitic.'" *Digital Music*, 812 F. Supp. 2d at 411 (quoting *In re New Motor Vehicles Canadian Exp. Antitrust Litig.*, 350 F. Supp. 2d 160, 207–08 (D. Me. 2004)). "Parasitic claims are '[w]here the unjust enrichment is based upon a predicate wrong, such as a tort, breach of contract or other wrongful conduct such as an antitrust violation.'" *Id.* (alteration in original) (quoting *Flonase*, 692 F. Supp. 2d at 542 n.13). "Conversely, unjust enrichment may provide an independent ground for restitution, and this is known as 'autonomous' restitution." *Id.* (quoting *Flonase*, 692 F. Supp. 2d at 542 n.13).

Here, all of the facts underlying Count VI are the same facts underlying the other claims, including the antitrust claims. (*See* Doc. 1 ¶ 379.) And even assuming that the allegations relevant to Count VI could somehow be disentangled from the claims based on the other alleged wrongs, Plaintiffs' purported "independent" claim for price gouging is, in effect, a claim that Plaintiffs "overpaid for the product for which they bargained." *Digital Music*, 812 F. Supp. 2d at 412. Such a claim is unavailing in cases like these. *See id.* ("Because autonomous restitution only exists in the absence of a violation of law, the Court will not inquire into the terms of the sale where, as here, a relatively comprehensive state and federal statutory and common-law scheme exists to proscribe the conduct of which Plaintiffs complain."). The court concludes that Teva is entitled to dismissal of Count VI insofar as it is brought under the laws of jurisdictions that apply *Illinois Brick*.[38]

This brings the court to Teva's second argument: that an "adequate remedy at law" precludes Count VI insofar as it is brought under the laws of the jurisdictions that do not apply *Illinois Brick*. Plaintiffs assert that Teva's argument on this point is "premature because there is as of yet no damage award, much less one threatening duplicative or inefficient liability" and because federal law authorizes pleading in the alternative. (Doc. 58 at 77–78.) Citing *Tomasella v. Nestlé USA, Inc.*, 962 F.3d 60, 69 (1st Cir. 2020), Teva insists that "[t]he *availability* of a legal remedy bars Plaintiffs' claims; viability is irrelevant." (Doc. 66 at 38 n.31.)

Initially, a blanket dismissal of the balance of Count VI would be inappropriate because the absence of an adequate remedy at law is not an element of the prima facie unjust-enrichment claim in at least some of the remaining jurisdictions. *See Miami Products*, 2022 WL 3701159,

[38] These are the jurisdictions listed in footnote 35 of Teva's motion (Doc. 49 at 86 n.35), except for Illinois, which—as the court concludes above—does not apply the *Illinois Brick* rule.

at *5. More generally, the court agrees with Plaintiffs that it would be premature to dismiss the remaining unjust-enrichment claims because those claims are pled in the alternative as authorized by Fed. R. Civ. P. 8(d). *Cf. Mooers v. Middlebury Coll.*, No. 20-cv-00144, 2021 WL 4225659, at *8 (D. Vt. Sept. 16, 2021) (holding that it would be premature to dismiss plausible unjust-enrichment claim that was pled in the alternative to a breach-of-contract claim); *Conn. Invs. LLC v. KDP, LLC*, No. 20-cv-179, 2021 WL 3519709, at *8 (D. Vt. Apr. 29, 2021) (declining to dismiss unjust-enrichment claim before resolution of breach-of-contract claim because Rule 8(d) authorizes pleading in the alternative).

Teva's reliance on *Tomasella* is misplaced. The court in that case did state that "[i]t is the availability of a remedy at law, not the viability of that remedy, that prohibits a claim for unjust enrichment." 962 F.3d at 82–83 (quoting *Shaulis v. Nordstrom, Inc.*, 865 F.3d 1, 16 (1st Cir. 2017)). But this court finds it unclear whether that statement is limited only to Massachusetts law. If it is so limited, then it does not affect any issue in this case because the court has already ruled that *Illinois Brick* bars the Massachusetts unjust-enrichment claim. If the *Tomasella* court intended its statement to apply more broadly, the court respectfully declines to follow it in light of this court's holdings that an unjust-enrichment claim can be pled in the alternative.

4. State Statute of Limitations Issues

The court concluded above that the limitations provisions of 15 U.S.C. § 15b do not apply to claims brought under 15 U.S.C. § 26 and thus that statute of limitations is not an impediment to the claims in Count IV. The analysis is different, however, for the claims brought under state law.

As noted above, the relevant lawsuits and citizen petitions were all filed more than seven years before Plaintiffs filed this federal suit in August 2022. Teva asserts that Plaintiffs' state-law claims challenge conduct dating to 2006, and that those claims are barred under the applicable four- to six-year state statutes of limitations. (Doc. 49 at 87; *see also* Doc. 49-3 (Teva's summary of statutes of limitations for state-law claims).) Plaintiffs maintain that their claims are timely for three reasons. First, they assert that Teva engaged in fraudulent concealment, thereby tolling all statutes of limitations until 2020, when the United States government brought the AKS lawsuit and when Congress issued the House Report. (*See* Doc. 58 at 79.) Second, Plaintiffs argue that their claims did not accrue until the House Report was released in 2020. (*Id.* at 85.) Third, Plaintiffs invoke the continuing-violations doctrine on the grounds that Teva's alleged scheme and Plaintiffs' alleged damages continued until at least 2019. (*Id.* at 86.)

The parties' respective appendices labeled "B" include their summaries of the positions on each of Plaintiffs' three arguments against dismissal on statute-of-limitations grounds. (*See* Doc. 49-2; Doc. 58-2.) In its reply memorandum, Teva maintains that "Plaintiffs have no valid justification for presenting such untimely challenges." (Doc. 66 at 39.) And according to Teva, "at a minimum, Plaintiffs should be precluded from reaching outside the limitations period to prop up their claims." (*Id.*) Teva further offers arguments against Plaintiffs' tolling, accrual, and continuing-violations theories. (*Id.* at 39–42.)

The court notes at the outset that it "may dismiss a claim on statute-of-limitations grounds at the pleadings stage 'if [the] complaint clearly shows the claim is out of time.'" *Whiteside v. Hover-Davis, Inc.*, 995 F.3d 315, 319 (2d Cir. 2021) (alteration in original; quoting *Harris v. City of New York*, 186 F.3d 243, 250 (2d Cir. 1999)). The court is mindful that

"[b]ecause a statute of limitations defense can be highly fact dependent, a motion to dismiss is often not the appropriate stage to raise affirmative defenses like the statute of limitations." *Russo v. Navient Sols., LLC*, No. 16-cv-00316, 2018 WL 1474354, at *13 (D. Vt. Mar. 23, 2018) (quoting *Canon U.S.A., Inc. v. Cavin's Bus. Sols., Inc.*, 208 F. Supp. 3d 494, 501 (E.D.N.Y. 2016)). Teva bears the burden of "demonstrating the statute of limitations bars Plaintiff[s'] claims." *Id.*

a. Accrual and the Discovery Rule

Anticipating a statute-of-limitations argument, the complaint invokes the "discovery rule" and asserts that:

> Plaintiffs and the members of the Class had no knowledge of the combination or conspiracy alleged herein, or of facts sufficient to place them on inquiry notice of the claims set forth herein, until August and September of 2020, when the government filed its complaint related to Teva's scheme to defraud Medicare [the AKS lawsuit] and the House Committee released its report [the House Report].

(Doc. 1 ¶ 235.) Teva asserts that under the law of 15 jurisdictions, antitrust claims accrue when a defendant commits an act that injures a plaintiff's business, not when the plaintiff discovers the injury. (*See* Doc. 49 at 94.) Teva further asserts that, where it is applied, the discovery rule "requires a plaintiff to inquire into the existence of a cause of action when the plaintiff has access to information that would prompt a reasonable party to do so." (*Id.* (quoting *Hightower v. Celestron Acquisition, LLC*, No. 20-cv-03639, 2021 WL 2224148, at *9 (N.D. Cal. June 2, 2021)).)

Although it might be natural to start with the questions of accrual and the discovery rule, the court concludes that the analysis below makes it unnecessary to resolve the parties' disputes on those issues. The court proceeds to the question of fraudulent concealment.

b. Fraudulent Concealment

The court begins with the question of fraudulent concealment as a basis for tolling the limitations periods. The court is mindful that "[r]esolution of a claim of fraudulent concealment so as to toll the statute of limitations is 'intimately bound up with the facts of the case'" and is generally not proper on a Rule 12(b)(6) motion. *Hinds County v. Wachovia Bank N.A.*, 700 F. Supp. 2d 378, 400 (S.D.N.Y. 2010) (quoting *In re Mercedes-Benz Anti-Trust Litig.*, 157 F. Supp. 2d 355, 374 (D.N.J. 2001)); *see also Allen v. Dairy Farmers of Am., Inc.*, No. 09-cv-230, 2014 WL 2610613, at *23 (D. Vt. June 11, 2014) ("[W]hether a plaintiff has shown fraudulent concealment is generally a question of fact for the jury.").

The parties both cite the following passage from *State of New York v. Hendrickson Bros.* regarding the elements required to toll the limitations provision of 15 U.S.C. § 15b due to fraudulent concealment:

> [A]n antitrust plaintiff may prove fraudulent concealment sufficient to toll the running of the statute of limitations if he establishes (1) that the defendant concealed from him the existence of his cause of action, (2) that he remained in ignorance of that cause of action until some point within four years of the commencement of his action, and (3) that his continuing ignorance was not attributable to lack of diligence on his part.

840 F.2d 1065, 1083 (2d Cir. 1988). Teva challenges the sufficiency of Plaintiffs' allegations as to the elements of tolling on a fraudulent-concealment theory.[39] The court considers Teva's arguments in turn.[40]

i. Concealment

Teva asserts "[t]he overwhelming majority of states require an affirmative act of concealment before the doctrine can apply; mere passive nondisclosure is insufficient." (Doc. 49 at 89–90 & n.38.) And according to Teva, the complaint lacks any plausible allegations of affirmative concealment. (*Id.* at 91.) Plaintiffs contend, however, that Teva's conduct is "self-concealing" and thus Plaintiffs are not required to show that Teva took independent affirmative steps to conceal it. (Doc. 58 at 80; *see also* Doc. 1 ¶ 240.) In reply, Teva maintains that "there is no automatic extension for conduct that is supposedly 'self-concealing'" and that "Plaintiffs' authority to the contrary is limited to *federal* claims—it provides no basis to extend the limitations period for any of their state-law claims." (Doc. 66 at 40.)

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[39] Citing *Bonin v. Vannaman*, 929 P.2d 754 (Kan. 1996), Teva also asserts that Kansas does not recognize the doctrine of fraudulent concealment at all with respect to statutory violations. (Doc. 49 at 90.) The court agrees with Plaintiffs, however, that Teva overreads *Bonin*. The *Bonin* court relied on the statement in *McCoy v. Wesley Hospital & Nurse Training School* that the fraudulent concealment doctrine applied "only when relief is sought on the ground of fraud." 362 P.2d 841, 847 (Kan. 1961). But as the Tenth Circuit observed, "that statement of the law no longer appears to be true." *Baker v. Bd. of Regents*, 991 F.2d 628, 633 (10th Cir. 1993) (citing *Friends Univ. v. W.R. Grace & Co.*, 608 P.2d 936, 941 (Kan. 1980)). The *Bonin* decision postdates both *Baker* and *Friends*, but the holding in *Bonin* appears to be limited to causes of action for fraud, which is not present in this case. *See Bonin*, 929 P.2d at 762 (stating that the fraudulent-concealment doctrine "only tolls the time in which *a fraud action* may be filed if the plaintiff's claim for relief is validly grounded in fraud on its face" (emphasis added)).

[40] Although the test set forth in *Hendrickson* applies to antitrust claims, Teva does not argue that any different test applies to Plaintiffs' consumer-protection and unjust-enrichment claims.

Although the court's focus is on the sufficiency of Plaintiffs' allegations of concealment for purposes of state law, the court finds it helpful to begin by reviewing some of the observations from federal court decisions. As the Fourth Circuit has stated: "[F]ederal courts have developed different standards for determining whether antitrust plaintiffs have satisfied" the concealment element of the three-part test for fraudulent concealment tolling. *Supermarket of Marlinton, Inc. v. Meadow Gold Dairies, Inc.*, 71 F.3d 119, 122 (4th Cir. 1995). The standards developed in the federal courts "are denominated the 'self-concealing' standard, the 'separate and apart' standard, and the intermediate, 'affirmative acts' standard." *Id.*

The *Meadow Gold* court described the self-concealing standard as the standard that the Second Circuit adopted in *Hendrickson*:

> As indicated in *Bailey v. Glover* [88 U.S. 342 (1874)], the plaintiff may prove the concealment element by showing either that the defendant took affirmative steps to prevent the plaintiff's discovery of his claim or injury or that the wrong itself was of such a nature as to be self-concealing.

Hendrickson, 840 F.2d at 1083. Under this standard, according to *Meadow Gold*, "a plaintiff satisfies the first element merely by proving that a self-concealing antitrust violation has occurred." *Meadow Gold*, 71 F.3d at 122. Plaintiffs argue that this standard applies to their state-law claims. (*See* Doc. 58 at 80.)

"At the opposite end of the spectrum," according to *Meadow Gold*, "is the separate and apart standard in which a plaintiff is required to provide evidence, separate and apart from the acts of concealment involved in the defendants' antitrust violation, that the defendants affirmatively acted to conceal the plaintiff's claim." 71 F.3d at 122. Citing *Langer v. Simpson*, 533 N.W.2d 511, 522 (Iowa 1995), Teva contends that Iowa has adopted this restrictive standard. (Doc. 49 at 90.) Plaintiffs concede that Iowa requires acts of concealment to be supported with "evidence of affirmative steps independent of and in addition to the original wrongdoing."

Langner v. Simpson, 533 N.W.2d 511, 522 (Iowa 1995). Although Plaintiffs contend that they have plausibly alleged affirmative acts of concealment (Doc. 58 at 82), none of those alleged acts appear to be independent of the alleged wrongdoing. The court therefore concludes that Plaintiffs' allegations are insufficient to toll Iowa's four-year antitrust statute of limitations on a fraudulent-concealment theory. (*See* Doc. 49-3.)

The third category of standards for determining the "concealment" element is the "intermediate" so-called "affirmative acts" standard under which "a plaintiff must prove that the defendants affirmatively acted to conceal their antitrust violations, but the plaintiff's proof may include acts of concealment involved in the antitrust violation itself." *Meadow Gold*, 71 F.3d at 122. Teva cites cases from eleven jurisdictions stating that an "affirmative" act or conduct is required to establish tolling on a fraudulent-concealment theory. (*See* Doc. 49 at 90 n.38.) But Teva has not shown that the courts in those jurisdictions would decline to consider "acts of concealment involved in the antitrust violation itself." *Meadow Gold*, 71 F.3d at 122.[41]

Teva asserts that the allegations in the complaint "boil down to an objection that Teva did not publicize its alleged conduct—not that Teva engaged in concealment, active or otherwise." (Doc. 49 at 91.) But according to the complaint, Teva:

- "[A]ctively concealed its illegal payments to Medicare recipients by funneling them through CDF [Chronic Disease Fund] and TAF [The Assistance Fund]" (Doc. 1 ¶ 241);

[41] At least one of the listed jurisdictions explicitly demonstrates that the "affirmative act" requirement can coexist with the recognition that certain forms of conduct are inherently self-concealing. *See Vichi v. Koninklijke Philips Elecs., N.V.*, 85 A.3d 725, 789 & n.399, 797 & n.436 (Del. Ch. 2014) (recognizing the rule that an "affirmative act" is required as stated in *In re Tyson Foods, Inc.*, 919 A.2d 563, 585 (Del. Ch. 2007), and simultaneously stating that "price fixing schemes are inherently self-concealing").

- "[C]oncealed its efforts to induce payors to pay for Copaxone by paying pharmacies to not collect cost-sharing obligations from private health plan members and by causing pharmacies to report the full, undisclosed drug price when submitting claims to PBMs and private health plans" (*id.* ¶ 242);
- "[M]isrepresented why it introduced 40mg Copaxone and otherwise concealed its true motive of avoiding generic substitution" (*id.* ¶ 243); and
- "[C]oncealed its efforts to conspire with PBMs and specialty pharmacies to have generic prescriptions filled with Copaxone" (*id.* ¶ 244).

Drawing all reasonable inferences in Plaintiffs' favor, the court concludes that the complaint alleges more than nondisclosure of internal "budgeting figures, documents, or communications revealing its donations or contracting strategy." (Doc. 49 at 91.)

ii. Reliance

Citing *In re Magnesium Oxide Antitrust Litigation*, No. 10-5943, 2011 WL 5008090 (D.N.J. Oct. 20, 2011), Teva contends that the complaint lacks any allegation that Plaintiffs "relied on" any "act of concealment." (Doc. 49 at 92.) Plaintiffs argue that the *Magnesium Oxide* court was applying the Third Circuit's test for fraudulent concealment and that Teva's citation to the elements listed in *Hendrickson* means that Teva has conceded that "reliance" is not a required element. (Doc. 58 at 82.) Plaintiffs further assert that "[i]n any event, plaintiffs in *Magnesium Oxide* were ultimately found to have satisfied the Third Circuit's more stringent requirement based on similar allegations to those here." (*Id.* at 83 n.49 (citing *In re Magnesium Oxide*, No. 10-5943, 2012 WL 1150123, at *7–8 (D.N.J. Apr. 5, 2012)).) Teva maintains that Plaintiffs have made no attempt to show reliance and that "this is a state-law issue, and several states that require affirmative conduct likewise require reliance." (Doc. 66 at 41 & n.35.)

The court is not persuaded that Teva's citation to *Hendrickson* is equivalent to a concession that "reliance" is not required under the laws of the applicable state jurisdictions. Teva cited *Hendrickson* to introduce the elements of fraudulent concealment "generally." (Doc. 49 at 89.) But Teva's motion proceeds to specifically assert that "reliance" is required and that Plaintiffs have not satisfied that element. (*Id.* at 92.) Teva's specific argument governs over its earlier general citation to *Hendrickson* and there was no concession on this issue.

Teva lists six jurisdictions—Delaware, Hawaii, Illinois, Michigan, Mississippi, and South Dakota—that require "reliance" as an element of tolling based on fraudulent concealment. (Doc. 66 at 41 n.35.) But Teva has not supplied any analysis indicating that the "reliance" required in those jurisdictions is any different than the "reliance" required in the 2011 *Magnesium Oxide* decision. The court therefore concludes that, as to the six jurisdictions that Teva has identified, the result in this case would be the same as in *Magnesium Oxide*: dismissal without prejudice as time-barred but with leave to amend to adequately allege "reliance." *Magnesium Oxide*, 2011 WL 5008090, at *23. Nonetheless, the court is unpersuaded that dismissal is required for any of the claims in these jurisdictions for the separate reasons discussed below.

iii. Ignorance and Diligence

Teva further argues that "Plaintiffs do not plausibly allege that they exercised due diligence in investigating their claims." (Doc. 49 at 92.) Teva asserts that the complaint includes allegations that "generic uptake in this market was substantially slower than typical" and that this, "if true, should have placed Plaintiffs on inquiry notice of their claims." (*Id.*) Plaintiffs disagree, arguing that: (1) "Plaintiffs alleged due diligence in how they monitor and respond to high drug prices"; and (2) "Plaintiffs could not possibly have investigated 'their

claims' prior to August and September 2020, when the government disclosed previously non-public information" via the AKS lawsuit and the House Report. (Doc. 58 at 83.) Teva maintains that Plaintiffs have failed to allege that they took any steps to investigate the alleged Copaxone price increases, and that the conduct targeted in Plaintiffs' complaint was public at the time that it occurred. (Doc. 66 at 41.)

The parties dispute whether Plaintiffs had "inquiry notice" of their claims. The complaint asserts that:

> Plaintiffs and the members of the Class had no knowledge of the combination or conspiracy alleged herein, or of facts sufficient to place them on inquiry notice of the claims set forth herein, until August and September of 2020, when the government filed its complaint related to Teva's scheme to defraud Medicare [the AKS lawsuit] and the House Committee released its report [the House Report].

(Doc. 1 ¶ 235.) As noted above, Teva maintains that slow generic uptake for GA products put Plaintiffs on inquiry notice. (Doc. 49 at 92.) On this dispute, the court observes that "whether a plaintiff had sufficient facts to place it on inquiry notice is 'often inappropriate for resolution on a motion to dismiss under Rule 12(b)(6).'" *LC Cap. Partners, LP v. Frontier Ins. Grp.*, 318 F.3d 148, 156 (2d Cir. 2003) (quoting *Marks v. CDW Comput. Ctrs., Inc.*, 122 F.3d 363, 367 (7th Cir. 1997)). But the court does not need to decide whether making that determination is proper at this stage of this case.

According to *In re Processed Egg Products Antitrust Litigation*—a case on which Teva relies—a showing of inquiry notice[42] triggers an obligation on the party resisting a statute-of-limitations defense to allege "due diligence in order to invoke the fraudulent concealment doctrine." No. 08-md-2002, 2013 WL 4504768, at *4 (E.D. Pa. Aug. 23, 2013); *see also id.*

[42] Inquiry notice is "often called 'storm warnings' in the securities context." *Lentell v. Merrill Lynch & Co.*, 396 F.3d 161, 168 (2d Cir. 2005).

at *5 n.6 ("[A] defendant must show that storm warnings existed before a plaintiff must prove that it exercised due diligence."). Decisions from within the Second Circuit are in accord. *See Blue Cross & Blue Shield of N.J., Inc. v. Philip Morris, Inc.*, 113 F. Supp. 2d 345, 382 (E.D.N.Y. 2000) ("A defense of fraudulent concealment fails if the plaintiff had either actual or inquiry notice of its claims *and did not diligently and thoroughly investigate*." (emphasis added)); *Griffin v. McNiff*, 744 F. Supp. 1237, 1256 (S.D.N.Y. 1990) ("Inasmuch as plaintiffs were put on inquiry notice from the withdrawals, they may not rely on allegations of fraudulent concealment to avoid the limitations bar *unless they exercised due diligence in attempting to ascertain the facts related to the alleged fraud, but were nevertheless unable or prevented from discovering the nature of their claim*." (emphasis added)).

Anticipating this issue, the complaint explicitly asserts that "Plaintiffs exercised appropriate due diligence under the circumstances." (Doc. 1 ¶ 246.) That alleged diligence included monitoring drug prices. (*Id.*) But even assuming that Plaintiffs' efforts to monitor drug prices supports a finding of inquiry notice, the additional allegations in the complaint plausibly indicate that Plaintiffs diligently attempted to ascertain facts that might support claims against Teva but were unable to do so. Noting that Plaintiffs lacked subpoena power or other mechanisms to review Teva's internal records, the complaint alleges that "Plaintiffs lacked the ability to discover that the drug prices they were paying were *higher than they should have been* because of anticompetitive, fraudulent, or other deceptive conduct." (*Id.*)

The defense argues that "many aspects of Teva's purported 'scheme' were public facing, such as its launch of Copaxone 40 mg and its DAW messaging." (Doc. 49 at 91.) Nothing in the complaint contradicts Teva's suggestion that Plaintiffs monitored the available public information about Teva's activities related to Copaxone. But significant information in the AKS

lawsuit and the House Report was not available to Plaintiffs before 2020. The inclusion of that information in those proceedings plausibly indicates that it is material—if not essential—to the claims in the AKS lawsuit and the findings in the House Report. It is likewise plausible that, despite Plaintiffs' efforts to monitor Teva's public activities, Plaintiffs lacked a sufficient basis to bring the claims in their complaint until the AKS lawsuit and the House Report revealed the previously non-public information.

Teva faults Plaintiffs for failing to file their lawsuit until August 2022—two years after the AKS lawsuit and the House Report became public, and a year after Mylan sued Teva on antitrust theories.[43] (Doc. 49 at 93–94.) Teva's argument on this point is not trivial; as other courts have held, "a plaintiff who invokes equitable tolling to suspend the statute of limitations must bring suit within a reasonable time after he has obtained, or by due diligence could have obtained, the necessary information." *Cada v. Baxter Healthcare Corp.*, 920 F.2d 446, 453 (7th Cir. 1990) (Posner, J.). But given the complexity of the factual and procedural history underlying Plaintiffs' allegations, the court finds no basis at this time to rule that Plaintiffs waited too long after the 2020 revelations to file this suit.

For all of the above reasons, the court concludes that Plaintiffs have adequately pleaded fraudulent concealment for all of the relevant jurisdictions except those specifically identified above.

c. Continuing-Violations Doctrine

The court considers the continuing-violations doctrine for the jurisdictions where, for the reasons discussed above, Plaintiffs' fraudulent-concealment allegations are insufficient to toll the

[43] As the court noted in its 2022 Order on Teva's Motion to Transfer or Stay (Doc. 45), Mylan sued Teva in June 2021. *See* Complaint, *Mylan Pharms. Inc. v. Teva Pharms. Indus. Ltd.*, No. 21-cv-13087 (D.N.J. June 29, 2021), ECF No. 1.

statutes of limitations. Teva recognizes that, under the continuing-violations doctrine, "a new cause of action accrues each time the plaintiff is injured by an act of the defendant." *Allen v. Dairy Farmers of Am., Inc.*, No. 09-cv-230, 2014 WL 2610613, at *24 (D. Vt. June 11, 2014) (quoting *In re Buspirone Patent Litig.*, 185 F. Supp. 2d 363, 378 (S.D.N.Y. 2002)).[44] But Teva argues that some jurisdictions do not recognize the continuing-violations doctrine, and further argues that "even where the doctrine does apply, it would provide no basis to recover damages on purchases made outside the limitations period." (Doc. 49 at 87.)

As to Teva's latter point, the court agrees with Plaintiffs that it is unnecessary at this stage to determine the scope of any potential recovery under any of the relevant state laws. As courts in other antitrust cases involving statute-of-limitations issues have held: "What the applicable period for the calculation of damages may be does not need to be decided on this motion to dismiss." *In re K-Dur Antitrust Litig.*, 338 F. Supp. 2d 517, 551 (D.N.J. 2004). Teva has not offered any analysis on this issue or any attempt to distinguish *K-Dur*. It therefore remains to consider the availability of the continuing-violations doctrine in the relevant jurisdictions where the complaint does not adequately plead tolling based on fraudulent concealment: Iowa (because of Iowa's "separate and apart" standard) and the six jurisdictions that require "reliance"— Delaware, Hawaii, Illinois, Michigan, Mississippi, and South Dakota.

Iowa. Teva does not argue that the continuing-violations doctrine is unavailable in Iowa. (*See* Doc. 49 at 88–89.) The court's own research reveals no Iowa authority that definitively rejects the continuing-violations doctrine. *Cf. Bandstra v. Covenant Reformed Church*,

[44] Plaintiffs assert that there is a second, distinct form of the continuing-violations doctrine that is also applicable in antitrust cases. (*See* Doc. 58 at 86 & n.54.)

913 N.W.2d 19, 46 (Iowa 2018) ("Although the parties dispute whether we have in fact adopted the continuing-violations theory, we need not resolve that issue . . . .").

Delaware. Teva does not argue that the continuing-violations doctrine is unavailable in Delaware. (*See* Doc. 49 at 88–89.) The court's own research reveals no Delaware authority that definitively rejects the continuing-violations doctrine. *Cf. GI Assocs. of Del., P.A. v. Anderson*, 247 A.3d 674, 680 (Del. 2021) (under "continuous negligent medical treatment doctrine," a plaintiff can bring "a single cause of action for the entire continuum of negligent medical care if any part of it occurs within the time required by the statute of limitations"); *Kerns v. Dukes*, No. Civ.A.1999-S, 2004 WL 766529, at *4 (Del. Ch. Apr. 2, 2004) ("If there is a continuing wrong, the cause of action is timely so long as the last act evidencing the continuing wrong falls within the limitations period.").

Hawaii. Teva does not argue that the continuing-violations doctrine is unavailable in Hawaii. (*See* Doc. 49 at 88–89.) The court's own research reveals no Hawaii authority that definitively rejects the continuing-violations doctrine. *Cf. Garner v. State*, 223 P.3d 215, 233 (Haw. Ct. App. 2009) ("Hawai'i has long recognized that a continuing wrong may, in effect, toll the statute of limitations with respect to tortious conduct that is ongoing.").

Illinois. Teva relies on *Feltmeier v. Feltmeir*, 798 N.E.2d 75 (Ill. 2003), reasoning that the court in that case "declin[ed] to apply the doctrine to Illinois claims." (Doc. 49 at 88.) But the *Feltmeier* court actually applied the doctrine in that case. *See Feltmeier*, 798 N.E.2d at 89 ("[I]n the case of a continuing tort, *such as the one at bar*, a plaintiff's cause of action accrues, and the statute of limitations begins to run, at the time the last injurious act occurs or the conduct is abated." (emphasis added)). At most, *Feltmeier* recognizes that a case of "continual ill effects

from an initial violation" does not constitute a continuing tort. *Id.* at 85. Teva has not argued that this distinction applies to Plaintiffs' claims under Illinois law.

Michigan. Teva cites two cases regarding the continuing-violations theory in Michigan. First, Teva relies on the *Lamictal* case, cited above. But that decision does not reject the availability of the "continuing-wrongful-acts" doctrine in Michigan. *Lamictal*, 172 F. Supp. 3d at 747. Instead, like *Feltmeier*, *Lamictal* recognizes that "[a] continuing wrong is established by continual tortious *acts*, not by continual harmful effects from the original, completed act." *Id.* (quoting *Horvath v. Delida*, 540 N.W.2d 760, 763 (Mich. Ct. App. 1995)). Teva has not argued that this distinction applies to Plaintiffs' claims under Michigan law.

Second, Teva cites *In re Pre-Filled Propane Tank Antitrust Litigation*, in which the federal court recognized that "[t]he Michigan Supreme Court has not determined if the continuing violations doctrine applies to claims brought under its antitrust laws" but predicted that the Michigan Supreme Court would adopt the doctrine. No. 14-02567, 2019 WL 4796528, at *10 (W.D. Mo. Aug. 21, 2019). Teva therefore appears to cite *Pre-Filled Propane* for the narrower proposition that damages on the Michigan claims are unavailable for purchases made outside of Michigan's four-year statute of limitations. *See id.* at *4 n.4. However, as noted above, it is unnecessary for the court to determine the applicable period for the calculation of damages at this stage of the case. *K-Dur*, 338 F. Supp. 2d at 551.

Mississippi. The *Pre-Filled Propane* decision states that "the Court is not aware of a Mississippi decision that discusses the continuing violation doctrine in any context" and that "[g]iven the uncertainty in Mississippi caselaw, the Court is unable to find that current precedent foreshadows the Mississippi Supreme Court adopting the continuing violation doctrine under the Mississippi Antitrust Act." 2019 WL 4796528, at *13. Similarly, the court in *In re Opana ER*

Antitrust Litigation stated that it could not find any case from Mississippi adopting the "continuing violation" doctrine in the antitrust context and concluded that "[i]n light of the unsettled nature of this doctrine . . . the Court declines to toll the statute of limitations . . . under . . . Mississippi law." 162 F. Supp. 3d 704, 725 (N.D. Ill. 2016).

The court respectfully declines to follow *Pre-Filled Propane* and *Opana* on this issue. Like the district courts in those cases, this court has found no Mississippi cases discussing a "continuing violations" doctrine. But the same doctrine goes by a few different names. *See, e.g.*, *Malek v. AXA Equitable Life Ins. Co.*, No. 20-CV-04885, 2023 WL 2682408, at *6 n.4 (E.D.N.Y. Mar. 29, 2023) ("New York courts sometimes refer to the continuing violation doctrine as the continuing wrong doctrine."), *appeal docketed*, No. 23-992 (2d Cir. June 30, 2023). And Mississippi does recognize a "continuing wrong" or "continuing tort" doctrine. *See, e.g.*, *Cooley v. Pine Belt Oil Co.*, 334 So.3d 118, 127 (Miss. 2022) (en banc). At present, this court sees no reason why that doctrine would not be available in a Mississippi antitrust case.

South Dakota. Teva does not argue that the continuing-violations doctrine is unavailable in South Dakota. (*See* Doc. 49 at 88–89.) The court's own research reveals no South Dakota authority that definitively rejects the continuing-violations doctrine. *Cf. Robinson-Podoll v. Harmelink, Fox & Ravnsborg L. Off.*, 939 N.W.2d 32, 47 (S.D. 2020) ("Generally, when a tort involves a continuing injury, the cause of action accrues and the statute of limitations commences when the wrong terminates." (quoting *Alberts v. Giebink*, 299 N.W.2d 454, 456 (S.D. 1980))).

For all of the above reasons, the court concludes that Teva has not shown that any of the relevant statutes of limitations bar Plaintiffs' state-law claims. It remains to consider the Rule 12(b)(2) motion that Teva Pharmaceutical Industries, Ltd. has filed.

II. Teva Pharmaceutical Industries, Ltd.'s Rule 12(b)(2) Motion to Dismiss

Plaintiffs have the burden to show that the court has personal jurisdiction over Teva Pharmaceutical Industries, Ltd. ("Teva Israel").[45] *Gater Assets Ltd. v. AO Moldovagaz*, 2 F.4th 42, 52–53 (2d Cir. 2021) (citing *In re Magnetic Audiotape Antitrust Litig.*, 334 F.3d 204, 206 (2d Cir. 2003) (per curiam)). Because no evidentiary hearing has been held in this case, "Plaintiffs need only make a prima facie showing of personal jurisdiction over the defendant." *Lelchook v. Société Générale de Banque au Liban SAL*, 67 F.4th 69, 75 (2d Cir. 2023) (quoting *Cholé v. Queen Bee of Beverly Hills, LLC*, 616 F.3d 158, 163 (2d Cir. 2010)). The court may consider Plaintiffs' pleadings and affidavits, which must be construed in the light most favorable to Plaintiffs and with all doubts resolved in Plaintiffs' favor. *In re Terrorist Attacks on Sept. 11, 2001*, 714 F.3d 659, 673 (2d Cir. 2013).

There are three requirements for a court to exercise personal jurisdiction over a defendant: "(1) the plaintiff's service of process upon the defendant must have been procedurally proper; (2) there must be a statutory basis for personal jurisdiction that renders such service of process effective; and (3) the exercise of personal jurisdiction must comport with constitutional due process principles." *Fuld v. Palestine Liberation Org.*, 82 F.4th 74, 85 (2d Cir. 2023) (internal quotation marks omitted). Teva Israel does not assert any procedural fault with service of process. But the parties dispute issues relating to the second and third requirements for the exercise of personal jurisdiction. The court begins with the question of the adequacy of a statutory basis for personal jurisdiction.

[45] Also referred to as "Teva Ltd." in the complaint. (Doc. 1 ¶ 21.)

A. Statutory Basis for Personal Jurisdiction

As discussed above, the complaint seeks relief under the Clayton Act. (Doc. 1 ¶ 296 (citing 15 U.S.C. § 26).) Section 12 of the Clayton Act includes the following provision:

> Any suit, action, or proceeding under the antitrust laws against a corporation may be brought not only in the judicial district whereof it is an inhabitant, but also in any district wherein it may be found or transacts business; and all process in such cases may be served in the district of which it is an inhabitant, or wherever it may be found.

15 U.S.C. § 22. The Second Circuit has recognized that § 22 contains two parts:

> The part before the semicolon addresses venue, permitting antitrust actions against corporations to be maintained "not only in the judicial district whereof [the corporate defendant] is an inhabitant, but also in any district wherein it may be found or transacts business." The part after the semicolon provides for worldwide service of process and, therefore, the exercise of personal jurisdiction "in such cases."

Daniel v. Am. Bd. of Emergency Med., 428 F.3d 408, 422 (2d Cir. 2005) (alteration in original). The Second Circuit has acknowledged a circuit split on the relationship between venue and service of process in § 12 and has joined the circuits holding that "the plain language of Section 12 indicates that its service of process provision applies (and, therefore, establishes personal jurisdiction) only in cases in which its venue provision is satisfied." *Id.* at 423.

Teva Israel argues that Plaintiffs have not established venue under § 22. (Doc. 48 at 18.) Teva Israel first raises a procedural argument, asserting that the complaint relies upon the general venue statute, 28 U.S.C. § 1391, without any reference to the Clayton Act. (*See* Doc. 48 at 19.) Plaintiffs maintain that the federal rules do not require complaints to specifically plead the legal basis for venue. (Doc. 57 at 12 n.2.) The court agrees with Plaintiffs on this point and rejects Teva Israel's suggestion that Plaintiffs might be barred from establishing venue under § 22 merely because the complaint does not cite that statute. *See Rocket Jewelry Box, Inc. v. Noble Gift Packaging, Inc.*, 869 F. Supp. 152, 154 (S.D.N.Y. 1994) ("The plaintiff need not include in

his complaint an allegation showing proper venue."); *cf. Fox v. Peterson*, No. 10-CV-6240, 2010 WL 11545717, at *6 (W.D.N.Y. May 13, 2010) ("Although plaintiffs did not plead § 1391(b)(1) in the complaint, that does not bar the Court from considering it as an alternative basis for venue."); *see also* 5 Charles Alan Wright et al., Federal Practice and Procedure § 1206 (4th ed.) (complaint need not state the grounds for personal jurisdiction).

As to the substantive application of § 22 in this case, Teva Israel asserts that Plaintiffs have failed to allege that Teva Israel is an "inhabitant" of Vermont or that it can be "found" here, or that Teva Israel "transacts business" in Vermont. (Doc. 48 at 20.) Plaintiffs disagree with the Second Circuit's interpretation of § 22 (*see* Doc. 57 at 13 n.3) but recognize that *Daniel* is the law in this circuit and is binding on the district court. Consistent with their position in the complaint (*see* Doc. 1 ¶¶ 20–22), Plaintiffs argue that even under *Daniel*, venue is proper in the District of Vermont for purposes of the Clayton Act "because Teva Israel 'transacts business' in this forum through its subsidiaries," with the subsidiaries acting as Teva Israel's "agents and/or alter egos." (Doc. 57 at 8.) Teva Israel maintains that the contacts of its United States affiliates do not establish personal jurisdiction. (Doc. 67 at 13.)

The phrase "transacts business" as it appears in § 22 refers to "the practical, everyday business or commercial concept of doing business or carrying on business of any substantial character." *Daniel*, 428 F.3d at 428 (quoting *United States v. Scophony Corp. of Am.*, 333 U.S. 795, 807 (1948)). "A parent-subsidiary relationship may form a basis for the exercise of Clayton Act jurisdiction." *All Star Carts & Vehicles, Inc. v. BFI Canada Income Fund*, 596 F. Supp. 2d 630, 637 (E.D.N.Y. 2009) (citing *Scophony*, 333 U.S. at 808); *see also Reynolds Metals Co. v. Columbia Gas Sys., Inc.*, 669 F. Supp. 744, 748 (E.D. Va. 1987) ("Under certain circumstances, the parent company of a wholly-owned subsidiary may be subject to jurisdiction and venue

under § 12 of the Clayton Act for the adjudication of antitrust claims in the state in which the subsidiary transacts business."). But the corporate parent of a subsidiary that transacts business in a forum does not itself necessarily "transact business" in the forum. *See Dennis v. JPMorgan Chase & Co.*, 343 F. Supp. 3d 122, 199 (S.D.N.Y. 2018) ("Allegations that certain of these defendants are parent companies of subsidiaries that transact business in New York do not suffice to show that the parent companies transact business in New York.").

To assess whether Teva Israel "transacts business" in Vermont through its subsidiaries, one consideration is whether the subsidiaries required Teva Israel's "constant supervision and intervention." *Scophony*, 333 U.S. at 815. Notably, the analysis does not require Plaintiffs to prove that Teva Israel exercised "[p]ervasive control" over its subsidiaries as in a veil-piercing context. *In re Vitamin C Antitrust Litig.*, No. 06-MD-1738, 2012 WL 2930109, at *7 (E.D.N.Y. July 18, 2012) (citing *All Star Carts & Vehicles*, 596 F. Supp. 2d at 637). The corporate parent's control over its subsidiary is a relevant consideration, but the court respectfully declines to follow *Reynolds Metals* insofar as that case equates the "transacts business" inquiry under § 22 with a veil-piercing analysis. *See Reynolds Metals*, 669 F. Supp. at 748 (citing *King v. Johnson Wax Assocs.*, 565 F. Supp. 711, 718 (D. Md. 1983)).

Teva Israel correctly observes that Plaintiffs' allegations regarding its conduct in this case differ from the conduct of the corporate parent in *Scophony*. The British parent company in that case signed contracts that gave it controls "which taken in conjunction with the stock controls called for continuing exercise of supervision over and intervention in" the affairs of its American subsidiary. *Scophony*, 333 U.S. at 814. The complaint in this case does not allege similar contracts or stock controls. But just because the facts of this case differ from those of *Scophony*

does not necessarily mean that the outcome of the "transacts business" analysis must be different.

Consistent with *Scophony*, the court examines the "practical reality" of the business relationship and inquires "whether the subsidiary's business transactions are ones that the parent 'would have to undertake directly if the subsidiary did not exist to perform them.'" *In re Vitamin C Antitrust Litig.*, 2012 WL 2930109, at *5–6 (quoting *In re Tamoxifen Citrate Antitrust Litig.*, 262 F. Supp. 2d 17, 23 (E.D.N.Y. 2003)). A variety of factors are relevant to this pragmatic inquiry, including "a high rate of crossover of directors"; whether corporate formalities at the subsidiary are "scarce"; and whether the parent "directly funded" the subsidiary's day-to-day activities. *Id.* at *6. Teva asserts that none of those factors are present here. (Doc. 67 at 12.)

The complaint does not itself speak directly to those three particular factors. But no single factor is dispositive. *See id.* ("[T]he Supreme Court and the Second Circuit have made clear that none of these individual factors should control the analysis."). And other factors weigh in favor of venue under § 22. The complaint alleges that Teva Pharmaceuticals USA, Inc. ("Teva USA") is a wholly-owned subsidiary of Teva Israel; that Teva Neuroscience, Inc. ("Teva Neuro") is a wholly-owned subsidiary of Teva USA; and that Teva Sales & Marketing ("Teva Sales") is a subsidiary of Teva Israel. (Doc. 1 ¶¶ 28–30; *see also id.* ¶ 32.) Of course, that alone is not dispositive, but the complaint also cites multiple allegations (*see id.* ¶¶ 34–35) regarding Teva Israel's relationships with its subsidiaries, including Teva USA, as discussed in *City & County of San Francisco v. Purdue Pharma L.P.*, 491 F. Supp. 3d 610 (N.D. Cal. 2020).

Teva Israel asserts that *Purdue Pharma* is "inapplicable." (Doc. 48 at 22; *see also id.* at 25 n.8.) The *Purdue Pharma* court was indeed analyzing a veil-piercing theory under

California's alter-ego doctrine—not under the venue provision of 15 U.S.C. § 22. *See Purdue Pharma*, 491 F. Supp. 3d at 635–36. But Plaintiffs maintain that "even if a different legal standard were applied, the underlying *factual findings* remain trenchant here: that is, the control, supervision, and direction by Teva Israel of its subsidiaries." (Doc. 57 at 28.) Teva Israel asserts that the different legal standard in *Purdue Pharma* means that "the factual allegations that were deemed sufficient there . . . do not support disregarding the corporate form here." (Doc. 67 at 14 n.7.)

Although the complaint includes an alter-ego theory (Doc. 1 ¶¶ 32–42), the court is not examining that theory here. As noted above, the transaction-of-business inquiry is not the same as an alter-ego/veil-piercing analysis. At this stage, the court is not considering the factual allegations in *Purdue Pharma* as a basis to disregard Teva Israel's corporate form. More importantly, Teva Israel does not dispute that the *Purdue Pharma* court relied on multiple factual allegations regarding Teva Israel's relationships with its subsidiaries.

The court is mindful that Teva Israel disputed many of the relevant allegations in *Purdue Pharma*. 491 F. Supp. 3d at 636. And the defense has supplied an affidavit from Teva USA Vice President and Deputy General Counsel Brian Shanahan that asserts, among other things, that Teva Israel "does not dominate, control, direct, or supervise the day-to-day operations" of Teva USA, Teva Neuro, Teva Sales, or their employees. (Doc. 48-1 ¶ 16.) But for purposes of Plaintiffs' prima facie case, this court notes that the allegations in *Purdue Pharma* supported determinations that:

- Teva Israel's "corporate history, structure, management, and officers demonstrates that it sought to fully integrate and control its subsidiaries";
- Teva Israel's control "encompasses its subsidiaries' day-to-day activities"; and

- Teva Israel's "shared financial structure demonstrates that it completely controlled its subsidiaries' finances."

Purdue Pharma, 491 F. Supp. 3d at 636–37. For present purposes, there are sufficient allegations to support the inference that Teva Israel would have to directly undertake the business activities of the relevant subsidiaries if the subsidiaries did not exist and that the "practical reality" of the business operations is that Teva Israel "transacts business" in Vermont sufficient to establish a basis for jurisdiction here under 15 U.S.C. § 22.

This conclusion makes it unnecessary to reach Plaintiffs' alternative arguments regarding Fed. R. Civ. P. 4(k)(2) and Vermont's long-arm statute. The court proceeds to the constitutional due process considerations.

B. Due Process Analysis

"To establish personal jurisdiction over a defendant, due process requires a plaintiff to allege (1) that a defendant has 'certain minimum contacts' with the relevant forum, and (2) that the exercise of jurisdiction is reasonable in the circumstances." *In re Terrorist Attacks*, 714 F.3d at 673. The court considers the parties' positions on both of these elements of the due process analysis.

1. Minimum Contacts

Because 15 U.S.C. § 22 provides for national service of process, "[t]he appropriate forum for purposes of determining whether the exercise of personal jurisdiction would comport with due process is the United States, rather than [Vermont]." *Dennis*, 343 F. Supp. 3d at 202.

Considering the United States as the relevant forum, the court examines Plaintiffs' argument that "specific" personal jurisdiction is present in this case.[46]

"Specific personal jurisdiction exists in suits 'arising out of or related to the defendant's contacts with the forum.'" *Nat'l Union Fire Ins. Co. of Pittsburgh v. UPS Supply Chain Sols., Inc.*, 74 F.4th 66, 72 (2d Cir. 2023) (quoting *Porina v. Marward Shipping Co.*, 521 F.3d 122, 128 (2d Cir. 2008)), *cert. denied sub nom. UPS Supply Chain Sols., Inc. v. Eva Airways Corp.*, No. 23-420, 2024 WL 71971 (U.S. Jan. 8, 2024). Here, the complaint includes sufficient allegations of Teva Israel's minimum contacts with the United States. (*See* Doc. 1 ¶ 22.) These alleged contacts include intentionally accessing United States markets, marketing Copaxone in this country, and accessing the United States court system and administrative agencies. (*Id.*) The court concludes that Plaintiffs have made an adequate prima facie showing of minimum contacts between Teva Israel and the United States.

2. Reasonableness

Finally, Teva Israel argues that exercising personal jurisdiction over it would not be reasonable under the circumstances. (Doc. 48 at 16.) "The reasonableness inquiry requires the court to determine whether the assertion of personal jurisdiction over the defendant comports with 'traditional notions of fair play and substantial justice' under the circumstances of the particular case." *Waldman v. Palestine Liberation Org.*, 835 F.3d 317, 331 (2d Cir. 2016) (quoting *Daimler AG v. Bauman*, 571 U.S. 117, 126 (2014)). Because the court has already concluded that Plaintiffs have met their prima facie burden to show that minimum contacts are present, Teva Israel can defeat jurisdiction only by presenting "a compelling case that the

[46] Courts also recognize a doctrine of "general" jurisdiction, but that is not at issue in this case. (*See* Doc. 57 at 23 (asserting that the question of general jurisdiction is "inapposite").)

presence of some other considerations would render jurisdiction unreasonable." *Eades v. Kennedy, PC L. Offs.*, 799 F.3d 161, 169 (2d Cir. 2015) (quoting *Licci ex rel. Licci v. Lebanese Canadian Bank, SAL*, 732 F.3d 161, 173 (2d Cir. 2013)). Considerations relevant to this analysis include:

> (1) the burden that the exercise of jurisdiction will impose on the defendant; (2) the interests of the forum state in adjudicating the case; (3) the plaintiff's interest in obtaining convenient and effective relief; (4) the interstate judicial system's interest in obtaining the most efficient resolution of the controversy; and (5) the shared interest of the states in furthering substantive social policies.

Id. (quoting *Cholé*, 616 F.3d at 164).

The court concludes that Teva Israel has failed to present a compelling case of unreasonableness here. Litigating in Vermont would impose some burden on Teva Israel, but the court is unpersuaded that the burden would be unreasonable. Teva is one of the largest pharmaceutical companies in the world; it has a significant presence worldwide and in the United States. The court is not persuaded that litigating in Vermont would impose an excessive burden on Teva Israel. The United States has a more than "minimal" interest in adjudicating this case, and Plaintiffs have a strong interest in obtaining convenient and effective relief. The parties dispute whether Teva Israel was "involved" in any of the alleged unlawful conduct, but Plaintiffs are entitled to all reasonable inferences and dismissing Teva Israel at this stage of the case might deny Plaintiffs effective relief. Teva Israel offers no argument on any of the remaining "reasonableness" factors. The court concludes that Teva Israel has not made a sufficient showing that exercising jurisdiction would offend traditional notions of fair play and substantial justice.

Conclusion

Defendants' Rule 12(b)(6) Motion to Dismiss (Doc. 49) is GRANTED IN PART and DENIED IN PART. The motion is GRANTED as follows:

- The court dismisses Plaintiffs' antitrust damages claims under Connecticut, Rhode Island, and Utah state law arising before October 1, 2017, July 15, 2013, and May 1, 2006, respectively;
- The Puerto Rico antitrust claims are dismissed;
- The Utah antitrust claims are dismissed without prejudice to repleading that includes a Utah citizen or resident as a named plaintiff;
- The portions of Counts I and II that seek relief under California and Kansas antitrust law are dismissed insofar as those claims are based on unilateral conduct. This ruling does not affect any claims under Counts I and II that seek relief under California and Kansas antitrust law for concerted action, and the court's conclusion here is without prejudice to an amended pleading if discovery reveals evidence of concerted action with respect to the alleged sham litigation or citizen petition process;
- Count V is dismissed insofar as it is based upon Mass. Gen. Laws ch. 93A, § 11;
- Count VI is dismissed insofar as it is brought under the laws of jurisdictions that apply *Illinois Brick*.

Defendants' Rule 12(b)(6) motion is DENIED insofar as it seeks dismissal of the Sherman Act claims in Count IV and is further DENIED in all other respects.

Teva Israel's Rule 12(b)(2) Motion to Dismiss (Doc. 48) is DENIED.

Dated at Burlington, in the District of Vermont, this 22nd day of January, 2024.

Geoffrey W. Crawford, Chief Judge
United States District Court